

**A RANDOMISED CONTROLLED EQUIVALENCY TRIAL ON  
WIPING WITH A CLOTH (NO SUCTION) VERSUS ROUTINE  
SUCTIONING OF ORONASOPHARYNX AT BIRTH, IN TERM  
NEONATES BORN ELECTIVE LSCS WITH CLEAR LIQUOR**

*Dissertation submitted in partial  
fulfillment of the regulation for the final examination of*

DOCTOR OF MEDICINE (D.M)  
BRANCH – VII  
NEONATOLOGY



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**THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY**

**CHENNAI, TAMILNADU**

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# **CERTIFICATE**

**This is to certify that this dissertation entitled “A RANDOMISED CONTROLLED EQUIVALENCY TRIAL ON WIPING WITH A CLOTH (NO SUCTION) VERSUS ROUTINE SUCTIONING OF ORONASOPHARYNX AT BIRTH, IN TERM NEONATES BORN ELECTIVE LSCS WITH CLEAR LIQUOR” is a bonafide work done by Dr.J.ASHOK RAJA, Division of Neonatology, Institute of child Health and Research Centre, Government Rajaji Hospital, Madurai Medical College, Madurai under my guidance and supervision in partial fulfillment of the regulations of The Taminadu Dr.M.G.R. Medical University for the award of Doctor of Medicine (D.M) Branch – VII (Neonatology) during the academic period August 2011 to August 2014.**

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## **DECLARATION**

I, **Dr.J.ASHOK RAJA** solemnly declare that the dissertation titled **“A RANDOMISED CONTROLLED EQUIVALENCY TRIAL ON WIPING WITH A CLOTH (NO SUCTION) VERSUS ROUTINE SUCTIONING OF ORONASOPHARYNX AT BIRTH, IN TERM NEONATES BORN ELECTIVE LSCS WITH CLEAR LIQUOR”** has been prepared by me. This is submitted to The Tamilnadu Dr.M.G.R. Medical University, Chennai in partial fulfillment of the rules and regulation for the award Doctor of Medicine (D.M) Branch – VII (Neonatology) to be held in **August 2014**.

**Place :** Madurai

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**Date :**

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# INTRODUCTION

In ancient times, birth attendants tried to remove the secretions by using a cloth or by blowing through the mouth and nose, or using a finger to remove secretions.(1) Then as the science of Resuscitation started developing, the initial resuscitation practices started from routine suctioning of mouth and nose using a suction machine or bulb syringe. Now the Recent NRP (Neonatal Resuscitation programme) 2011 guidelines states that clear the airway if necessary and it can be done with a suction catheter, bulb syringe or by wiping with a cloth.(2)

In Indian context all the three methods are prevalent in different settings throughout the country. WHO and NRHM raised concerns about sterilizing the bulb syringes and the chances of infection using a towel. A Disposable suction catheter or Delee's mucus trap connected to a suction machine is used in many hospitals including our hospital. Observations on natural birth of mammals showed that, immediately after birth the mother animal licks over the face of the off spring, including the mouth and nose. This naturally wipes out all the secretions, and also gives tactile stimulation to the off spring to initiate breath.

These observations bring forth the thought that wiping the face with a clean cloth mimics natural phenomena, licking.



In the Pre NRP era, neonatal Resuscitation was started by wiping with a cloth and now again in the NRP era; we have come back to wiping with a cloth. Taking a U turn, recent guidelines roll back to where we started.

When we looked into the trials based on which these recommendations are made, there are only few (2-3) pilot studies and 2 RCTS done at the same center are available. Using a standard search criteria, (oronasopharyngeal suction, oral suction, Routine suction, Neonate, Birth, Resuscitation, delivery room resuscitation) and searching in PUBMED, CINAHEL, CTRI, EMBASE Databases we don't find any studies on Routine suction, from India. (Although studies on suctioning in meconium stained babies and endotracheal suctioning are available). Recently, Cochrane has also published a protocol for metaanalysis, searching for randomized controlled trials on Routine suction at birth. It also said a large body of evidence is necessary to change practice.(3)

The paucity of literature in this essential topic stimulated us to do a randomized controlled trial in this topic.

Our hospital is a Tertiary care Medical College Hospital, with 14,000-15,000 annual deliveries, with 25-30% of delivered neonates requiring admission. Considering the large number of deliveries per day and the difficulty in randomising all the deliveries and the availability of manpower

round the clock, we decided to restrict the present study to apparently normal term Neonates born elective Lscs.

We also used pulseoximeter during resuscitation for the first time and we believe that this study will highlight the evidence in Routine suctioning practice, as well as bring out the merits and practical difficulties in using a pulseoximeter, in a high volume delivery setting.

We hope the experience and findings gained in this study will help future research in a broad population of Neonates.

# **REVIEW OF LITERATURE**

## **Benefits of suction**

Initially suctioning of the mouth, nose and pharynx were believed to help in expelling the pulmonary fluid out of the lung, then the other reasons thought for suctioning are, it facilitates air entry by reducing the airway resistance due to secretions, it prevents aspiration of mucus and meconium, and it acts as a stimulation to initiate breath.(3)

A brief review of the literature on fetal lung physiology, and the transitional changes at birth, helps in understanding the role of any resuscitative measure like suction in Routine care.

## **Fetal Lung**

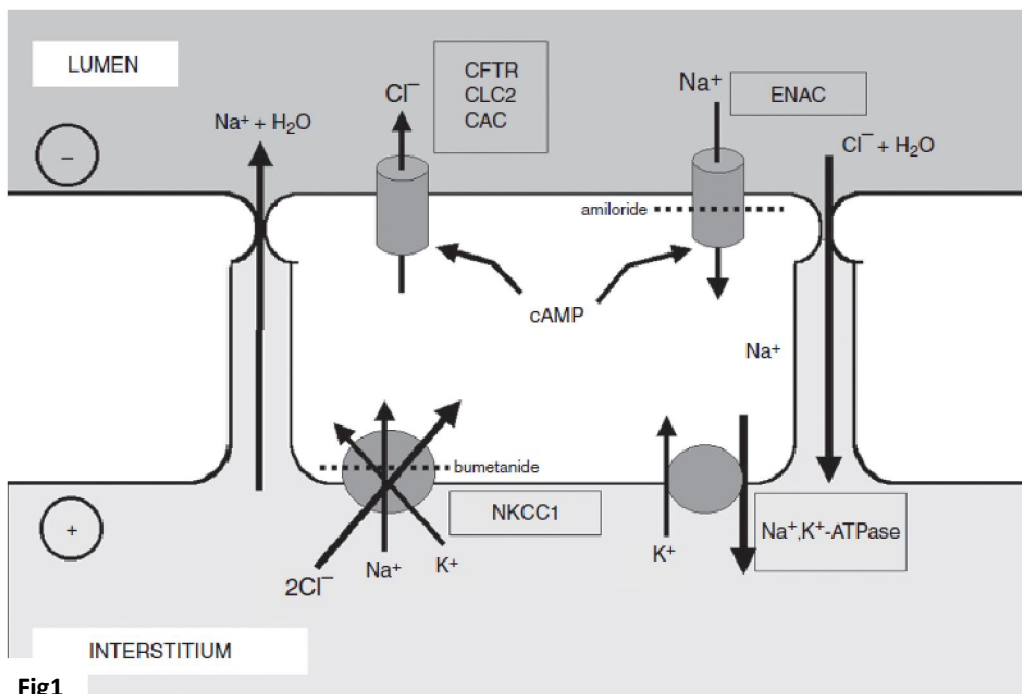
The fetal lung is filled with fluid. The fetus entirely depends on the placental circulation for gas exchange and nutrition. The fetal alveolar epithelial cell secretes the lung fluid by an active process. (4) The alveolar epithelium contains Cyclic - AMP dependent luminal chloride transporter.(Fig-1) The entry of chloride from the interstitium into the alveolar cell occurs by  $\text{Na}^+/\text{K}^+/\text{Cl}^-$  transporter at the basolateral membrane. This chloride within the cell is actively transported through the chloride transporter to the alveolar lumen. Secretion of chloride into the lumen

creates an electro negative gradient drawing sodium and water through the paracellular spaces. The lung fluid secretion increases with the growth of the fetus and the number of alveoli .only days before delivery, the fetal lung fluid secretion decreases.(4) However, this does not occur in preterm deliveries, thus delaying the transition at birth. The secreted lung fluid enters the tracheobronchial tree and into the oropharynx. From there, it is swallowed or expelled into the amniotic cavity.

### **Role of Labour:**

Term Rabbits delivered after the onset of labour either by C-section or by vaginal delivery, has lesser incidence of transient tachypnea (3%) compared to those born before the onset of labour (6%).(5)

This showed that the protective effect of labour is not due to the “thoracic squeeze” in vaginal delivery, but due to the surge of catecholamines during labour. They act on the Beta adrenergic receptor at the lung epithelium, switching it from the secretory state to the absorptive state.(6)



**Fig1** Arrangement of ion transporters and pumps in the lung epithelia of fetal lung. Amiloride is a specific inhibitor of the epithelial sodium ( $\text{Na}^+$ ) channel (ENAC), and bumetanide blocks  $\text{Na}^+$ , potassium ( $\text{K}^+$ ), chloride ( $\text{Cl}^-$ ) cotransporter 1 (NKCC1). The "plus" and "minus" signs indicate polarity of the lumen with respect to the interstitium. CAC, Calcium-activated channel; cAMP, cyclic adenosine monophosphate; CFTR, cystic fibrosis transmembrane conductance regulator; CLC2, voltage-gated  $\text{Cl}^-$  channel 2.

As In Fig-1, the  $\text{Na}^+ \text{K}^+$  ATP-ase pump at the alveolar basolateral membrane and another, Cyclic AMP dependent, activated epithelial sodium channel (ENA), both aid in transporting sodium from the lumen to the alveolar interstitium. The positive electrochemical gradient due to sodium at the interstitium draws chloride ion and water through the Paracellular space. Then, this absorbed fluid in the interstitium, mostly enters the pulmonary circulation and 10-15% of the fluid, enter the lymphatic system.(5, 6)

**After Birth:**

The Positive airway pressure created by the first breath of a neonate further expels the fluid from the alveoli. In term newborn, most of the lung fluid is cleared within 2 hrs of spontaneous breathing. In animal studies a decrease in the paracellular resistance and an increase in the solute permeability of the lung epithelium at the onset of breathing is shown. This increases the lung fluid clearance after birth.(5)

**Normal Transition at Birth:**

Inutero, the fetus lives in a protected environment with a temperature 0.5°C higher than the maternal Body Temperature.(7)

At birth, the temperature gradient between the Neonate and the environment is much higher than that in intrauterine life and heat is lost over the skin. Until the Neonate produces heat from brown adipose tissue, Baby needs some assistance to retain its body temperature, (8)in the form of receiving the baby in prewarmed towels, drying the baby, and keeping the baby in warmer or over mothers chest.

The next important transition is the transition from a Placental to Pulmonary gas exchange system. At birth, the clamping of the cord cuts the oxygen supply and the Pco<sub>2</sub> raises, this stimulates the central and peripheral chemoreceptors. Further the exposure to relatively low environmental

temperature (Thermal) and the tactile stimulation stimulates the onset of first breath. Normally, a combination of these events, helps in establishing spontaneous breathing.(9)

Third is the circulatory adaptation. Inutero, the unexpanded lungs provides high pulmonary vascular resistance and only (10%) of the total cardiac output, flows through the lungs. The placenta attached to the systemic circuit of the fetus via umbilical artery, is a low resistance system, essential to transport gases and nutrients between the fetus and the maternal circulation. At birth, following cord clamping and removal of placenta from the systemic circuit, the systemic blood pressure rises. Following breathing, lung expansion occurs; the  $PO_2$  starts raises, relaxes the pulmonary vasculature, and decreases the pulmonary vascular resistance.(9, 10)

### **Pulse oximeter and Neonatal Resuscitation**

The fetal saturation values are <60% just before labour and can decrease upto 30% during labour. After the first breath of the Neonate, the saturation values continue to increase during the first 10minutes of life. (10)Hence most babies at birth will be cyanosed at birth and it may be difficult to assess the oxygen needs of the baby by looking at the colour. Hence the current NRP 2011 Guidelines replaced colour as an assessment

tool for ongoing resuscitation and recommends the use of pulse oximeter at delivery room for monitoring oxygenation.

The normal reference values for the first 10 minutes of life are shown in Table.

Targeted Pre-ductal SpO <sub>2</sub> After Birth	
1 min	60%-65%
2 min	65%-70%
3 min	70%-75%
4 min	75%-80%
5 min	80%-85%
10 min	85%-95%

Ranges of pre-ductal oximetry values during the first 10 minutes following birth of uncomplicated babies born at term. The ranges shown are approximations of the interquartile values reported by Dawson et al (*Pediatrics*. 2010;Jun; 125:e1340-1347) and adjusted to provide easily remembered targets.

Newer generation of pulse oximeters, with motion artifact technology and neonate specific probes, detect reliable values within 1-2 minutes after birth.(10) The probe is attached to the hypothenar eminence or the wrist of the neonates, the right hand preferred for recording Preductal saturation. To pick up signals early, the probe needs to be attached to the baby first, before connecting the probe to the machine. Pulseoximeter averages the

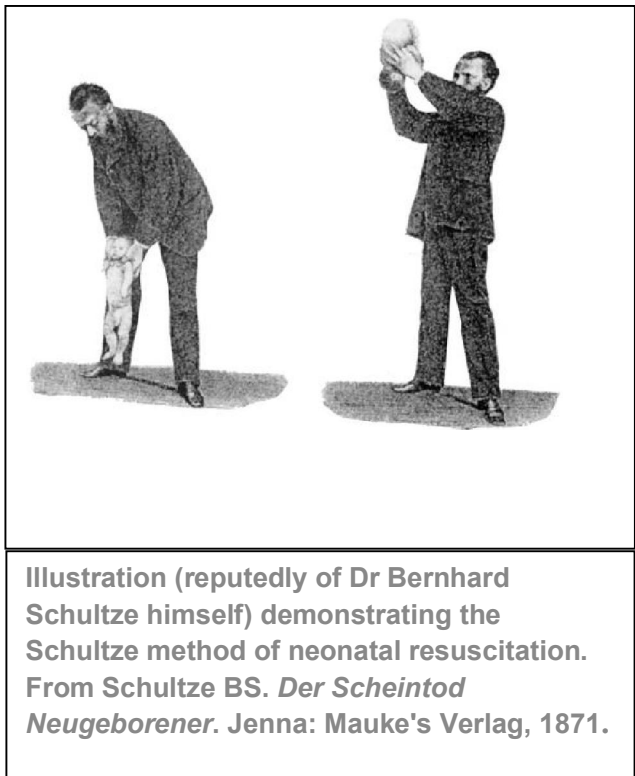
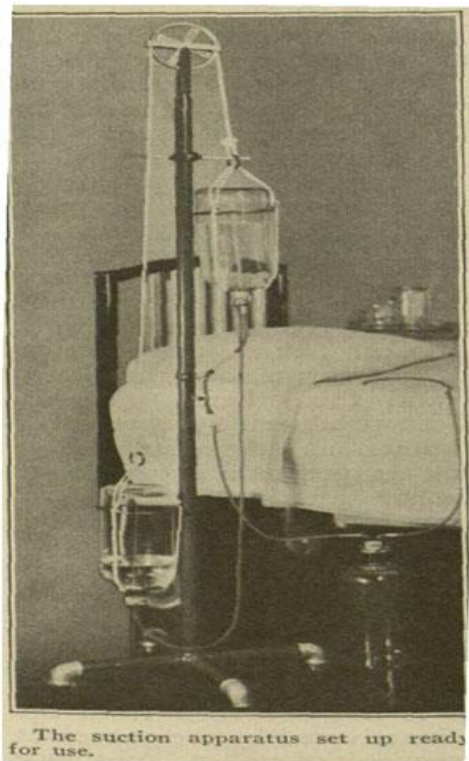


measurements every 2 seconds or 8 seconds depending on the preset averaging time in the machine. usually for routine recording in the ward, a 8 seconds averaging time which is more accurate is used and for resuscitation a two second averaging time ,to pickup signals quickly, is recommended.(9) Both disposable and reusable neonatal sensors are available. Pulseoximeter capable of storing recorded data and data transfer options are available for certain pulseoximeter, like the one we used for our study.(11)

Current NRP 2011 guidelines recommends pulseoximeter to be used when resuscitation is anticipated (e.g.: preterm), or when cyanosis is present or when supplementary oxygen is administered.

### **Historical Perspectives:**

In ancient history attempts of resuscitation with various techniques and devices have been described. The use of Bulb syringe was described as early as 980-1037 AD by Avicenna.(12) The Bible (Old Testament), mentions about the mouth to mouth breathing and intubation was described by Hippocrates in 460-380 BC itself. In the modern history, early in the Twentieth century 1910 to 1950, neonatal care was mostly a nursing task. The Baby's airway was cleaned of mucus using a gauze or suction or with a finger.(1)



Later, Tzardi and Davis found that babies undergoing primary apnea can be aborted in most babies by simply putting nasopharyngeal suction and administering oxygen.(13) Following various methods of resuscitation advocated by different practioners and the growth of applied physiology in medicine, In 1987 The American academy of pediatrics and American heart association (AHA) formed a Neonatal resuscitation program (NRP) and issued its first guidelines in 1987.The First guideline was based on the expert consensus and the knowledge from the cardiopulmonary resuscitation program of adults at that time, started by AHA.

## RECOMMENDATIONS FROM MAJOR BODIES REGARDING CLEARING THE AIRWAY

### NRP 2005:

Position, clear the airway (as required). Clear the airway with a bulb syringe or suction catheter.

**Excerpts from Neonatal resuscitation programme book 2011.**

### Clearing the airway in neonates born with clear amniotic fluid.

“Secretions *can be removed from the airway by wiping the nose and mouth with a towel or by suction catheter or suctioning with a bulb syringe*”.

In Neonates with copious secretions, head should be turned to the side to allow the collection of secretions in the cheek, which can be removed.

“Bulb syringe or a catheter attached to mechanical suction to remove any fluid blocking the airway, Can be used”.

- The negative pressure from the suction source should be adjusted (vacuum) to approximately 100 mm Hg.
- The mouth has to be suctioned before the nose.
- Deep or vigorous suction should not be done, because posterior pharynx stimulation can produce apnea or bradycardia.

- If bradycardia occurs during suctioning, stop suctioning and re evaluate the heart rate.
- Brief gentle suctioning with a bulb syringe is usually adequate.
- Suctioning, in addition, stimulates breathing.

Similarly for meconium stained Babies, NRP recommendations keep on changing over years.

A summary of changes is given below.

<b>NRP Guidelines</b>	<b>1970-80</b>	<b>2000</b>	<b>2005</b>	<b>2010</b>
Intrapartum suctioning	yes	yes	no	no
Intubation and suctioning all MSAF	yes	no	no	no
Selective suctioning of non vigorous MSAF	no	yes	yes	Yes*
*To continue same till enough evidence is available				

Current NRP 2011 recommends that vigorous Neonates stained with meconium needs only routine care. In depressed Neonates with meconium, oral and endotracheal suctioning is recommended, despite recent multicentric trials (14) not showing any clear benefit.

### **WHO; Guidelines on Basic Newborn Resuscitation 2012.(15)**

WHO recommends when a neonate born with clear amniotic fluid and actively cried at birth, there is no need of routine suction. (High quality evidence). Three studies are quoted as evidence with pooled mean oxygen

saturation levels 9.8% lower in the suction group. Among the three, 2 are from same center (Gungor study) and the third one is a pilot study.

But when a baby born with clear amniotic fluid requires positive pressure ventilation, suctioning can be given (low quality evidence).

## Oral nasal suctioning of Neonates born with clear amniotic fluid (15)

Outcome	No. of studies	Design	Limitations in methods	Precision	Consistency	Generalizability / directness	Overall quality of evidence	Pooled ES (95% CI)
<b>Oxygen saturation levels</b> (at 5 minutes of life)	3	RCTs	No serious limitations	Pooled effect significant, upper limit of CI indicates meaningful effect	Three studies, ES in same direction	From low-and middle-income country settings	<b>HIGH</b>	MD - 9.8% (- 10.2%, -9.4%)
<b>Normal Apgar scores</b> ( $\geq 9$ at 5 minutes after birth)	3	RCTs	Limitations in measurement	Pooled effect not significant, with wide CI	ES of studies with $<75\%$ weight consistent with no effect	Majority of evidence from developing countries	<b>LOW</b>	RR 0.54 (0.28 to 1.07)

The Meta analysis of existing RCTs showed that the pooled mean saturation difference at 5 minutes of life is 9.8% higher in the nosuction group compared to suction group.

## **STUDIES ON AIRWAY CLEARANCE & SUCTION**

### **1. Reduction in Airway Resistance:**

Dr. Prendiville studied airway resistance, time constant and compliance during 32 times of endotracheal suction in preterm ventilated babies (n=35). Compared to a reference population (n=36). There was a significant reduction in airway resistance and time constant, but no significant changes in compliance was noted.(16)

### **2. Other studies on ET Suction:**

In 1992, Evans (17) studied two groups of neonates on ventilator. One group was suctioned. Another group not suctioned. 6 out of 17 (6/17) Neonates in the suction group developed hypoxemia lasting for 3 minutes. No bradycardia or apnea was noted in the suction group. But increasing blood pressure during suction was noted in the study and it raised concerns about the risk of IVH during suction in preterm babies.

Similarly in another study by Perlman,(18) he found that increased cerebral blood flow velocity in anterior cerebral arteries occurs during suction ,in 35 ventilated preterms using transcranial Doppler.

Simbruner (19, 20) studied 10 neonates in 1981, by measuring transcutaneous Po<sub>2</sub>, blood pressure and heart rate during suction.

A significantly decreasing heart rate (144 to 123), blood pressure (44→ 42) (mean), and hypoxemia (5/10) were found during suction in neonates.

In a study by skov (20) using NIRS, it was observed that Preoxygenation alleviates the decrease in SaO<sub>2</sub>, and Brain oxygenation, during suction. But Preoxygenation does not affect the changes in PCO<sub>2</sub> and cerebral blood flows occur during suction.

In 2008 Kaiser (21) observed, prolonged increases of cerebral blood flow in ventilated neonates <1.5Kg, following suction. This raised the concerns about the Long term Brain injury due to suction.

Based on these studies, Routine Endotracheal suctioning in ventilated neonates is not advised. But blocking of Endotracheal tube is a life threatening problem, hence suction is advised when secretions are visible or evidence for tube block is present.

But, extrapolating the adverse effects of endotracheal suction to oro-Nasopharyngeal suction is difficult. During Endotracheal suction, suction catheter itself can produce partial obstruction of the tube and also the air in the distal airways can get sucked out. Similarly deeper suction like pharyngeal suction is known to stimulate vagal response producing Bradycardia, apnea or hypoxemia. But the question arises here is whether a



gentle oral suction is equivalently dangerous like endotracheal or deeper pharyngeal suction.

Studies addressing these issues on oronasopharyngeal suction are only very few.

Estol(22) in their study on Routine Catheter suction versus a control group in term Neonates, found no differences in respiratory function between the two groups. Also they found that the amount of aspirate was a miniscule of the total lung fluid. Hence suction, as a method to clear the lung fluid is not true.

In 1971, Corderro(23) noted apnea, bradycardia and lower oxygen saturations with oronasopharyngeal suction. These occur on deep and prolonged suction by using a nasogastric tube in 46 Neonates, where as the other group of 41 Neonates who received bulb syringe suction, does not developed bradycardia.

Carasco in Uruguay (1997)(24) did a controlled study of suction in term singleton Neonates with clear amniotic fluid. Fifteen Neonates received suctioning of oral and Nasopharynx using a suction catheter and 15 Neonates received no suction. The time taken to reach 92% saturation was lesser ( $6.8 \pm 1.8$  minutes) in the no suction group compared to suction group

(10.2 minutes  $\pm$  3.3). Similarly, the average value of SaO<sub>2</sub> was lower in the first 6 minutes of life in the suction group.

Similarly, in a pilot controlled study (25) in 2004, 10 Neonates were routinely suctioned using bulb sucker and the other group of 10 Neonates were not suctioned. The suction group took longer time to reach a saturation of 92% and had lower heart rate. After 10 minutes of life suction group started having higher SpO<sub>2</sub> levels than the group not suctioned and it sustained upto 20 minutes of life.

#### **Randomised controlled trials on routine suction:**

In a center at Turkey, Gungor (26) and his associates randomised term Neonates born vaginally, with clear liquor, into two groups. The First group (n = 70) received oronasopharyngeal suction with an 8F catheter and the other group received wiping with a towel to clear secretions. The no suction group reached a >92% saturation values early, (in 6 minutes) compared to the suction group (11 minutes.) The no suction group had lower mean heart rates from 3 to 6 minutes of life.

In 2005, the same group (27) did a similar RCT in elective LSCS term babies. The same results were replicated. The time to reach 92% - SaO<sub>2</sub> was 6 versus 11 minutes in no suction and suction groups respectively.

*Surprisingly, the no suction group had lower mean heart rates, although both the groups had heart rates within the normal range.*

This is in contrast to other pilot studies where the suction group developed bradycardia. (22) No adverse outcome with suction was noted in this trial. However the suction pressure in Gungor study was 30 mmHg, which is low when compared to the standard recommendation (100mmHg) by NRP.

Recently, a large randomised equivalency trial by Kelleher(28) and associates used bulb suction in 242 Neonates, and in another 246 Neonates, wiping with a towel was used immediately after birth.

The primary outcome, mean respiratory rate in the first 24 hrs was equal in the groups,  $51 \pm 8$  in wipe group, and  $50 \pm 6$  in the suction group. The secondary outcomes like mortality, morbidity was also not significantly different between the two groups. The trial concluded wiping with a towel is equally efficacious to bulb suction at birth in late preterm and term neonates, both in clear amniotic fluid and in vigorous meconium stained babies.

## JUSTIFICATION FOR PRESENT STUDY

Suctioning of airway is a very important day-day practice in neonatal resuscitation. Yet the studies in the topic are limited, that too well designed Randomized control trials are only three. We don't find any published studies/RCTS in Indian literature.

Major bodies based their recommendation on the two RCT's done at turkey and few pilot studies with small number (20) at developed nations. The coated references by major bodies itself has controversies.

- Lower heart rate in suction group – Waltman (25).
- Lower heart rate is no suction group – Gungor & associates (27).
- The SaO<sub>2</sub> levels stabilize after 10minutes and remain higher in bulb suction group – Waltman.
- The SaO<sub>2</sub> levels are higher in no suction group in first 1-6minutes of life – Gungor 2006 and Carassco study(24).

In this context we decided to do a RCT on routine suction after delivery.

We believe our study will contribute to a practice changing parameter i.e. the role of routine suction or wiping as a routine in Lscs deliveries.

- It will also bring out the application of pulseoximeter in delivery room and the difficulties in resuscitation in Indian scenario.

# **OBJECTIVES AND HYPOTHESIS**

## **Research Question**

Does wiping with a cloth is equally efficacious to suctioning of oronasopharynx with a machine, in term neonates born by elective Lscs, with clear amniotic fluid and cried at birth, in terms of the time duration to achieve a stable saturation of 92% and other short term hospital outcomes?

## **HYPOTHESIS**

In Term neonates born Elective Lscs with clear liquor and cried at birth, the difference between the mean time taken to reach 92 % saturation, in those neonates who underwent suctioning of oronasopharynx (using a Delees catheter connected to a suction machine) and those who underwent wiping of oronasopharynx at birth, will not differ by more than 2 minutes.

### **Primary Objective**

A Randomised controlled trial to compare the efficacy of wiping with a cloth to Routine suctioning of oronasopharynx using a suction machine, in term neonates delivered Elective Lscs with clear liquor, in the time taken for achieving a saturation value of 92%.

### **Secondary Objective**

To compare the efficacy of wiping with a cloth (No suction) and suctioning of oronasopharynx in Routine care in the following parameters.

1. Time to reach 85 % saturation and 95% saturation.
2. To compare the saturation values at 3, 5, 10, 15 minutes of life
3. To compare the proportion of neonates achieving a saturation target of 92%, 85%, 95% saturation at birth.
4. Need for advanced resuscitation by positive-pressure ventilation, intubation, chest compression, emergency medications, or a combination of these methods.
5. Apgar score at 5 minutes
6. Need for nicu admission & Length of stay in admitted babies.
7. Tachypnea, defined as a respiratory rate higher than 60 breaths per min, at any time in the first 24 hrs after birth.
8. Any Mortality in the first 28 days of life

## Outcome variables and measurement

The details of outcome variables and measurement for the above mentioned objectives are as mentioned in Table 1.

**Table 1: Outcome variables and measurements of various objectives**

<b>Objectives</b>	<b>Outcome variable</b>	<b>Outcome measurement</b>
Time taken for achieving a saturation value of 92%.	<b>Mean duration to reach 92% saturation</b>	Mean/median Minutes and seconds to reach 92% saturation in both groups. Time is measured from birth till the outcome is achieved in the Lscs theater, by noting the time displayed in the pulseoximeter.
Time to reach 85 % saturation and 95% saturation	Median Minutes to 85% saturation and 95% saturation	-as described above
To compare the saturation values at 3, 5, 10, 15 minutes of life	Mean saturation at 3,5,10,15 minutes	Mean saturation values at 3, 5, 10, 15 minutes after birth, derived from pulseoximeter data, compared between both the groups.
Number of babies reaching the saturation target of 92%, 85%, 95% at birth.	Proportion of neonates reaching 92%,85%,95%	Measured by manual recordings and pulseoximeter data.
Need for advanced resuscitation by positive-pressure ventilation, intubation, chest compression, emergency medications, or a combination of these methods	Proportion of babies requiring advanced resuscitation	Recorded in prescribed proforma and compared between both wipes (No suction) and suction Groups.

Apgar score at 5 minutes	Mean score at 5 minutes	Recorded during resuscitation in the proforma.
Need for nicu admission & length	Proportion of babies admitted and mean days of stay	Recorded from follow up of neonates at ward and admission and discharge registers
Tachypnea, defined as a respiratory rate higher than 60 breaths per min, at any time in the first 24 hrs after birth.	Proportion of neonates having tachypnea	- As described above
Mortality	Proportion of deaths	Death within 28 days of life is noted from follow up and death registers in ward.



# MATERIALS AND METHODS

## 1. DESIGN:

Randomized controlled equivalency trial with parallel group design.

## 2. PARTICIPANTS:

### Setting:

Term neonates born elective Lscs at Government Rajaji Hospital, Madurai.

**Period;** November 2013 to March 2014.

(4 months Recruitment, 1 month for follow up, and analysis).

### **A. Inclusion Criteria (all the following should be met)**

1. Singleton gestation
2. Elective lower segment cesarean delivery
3. Clear amniotic fluid
4. Term Neonates (37–42 wk) cried at birth and having good tone.

### **B. Exclusion Criteria**

1. Major congenital anomalies
2. Depressed (cried after tactile stimulation) or asphyxiated at birth
3. Meconium stained neonates at birth

4. Normal vaginal and emergency Lscs deliveries.
5. Preterm deliveries <37 weeks.
6. Precious deliveries.

### 3. INTERVENTION

- In the **suction group**, oronasopharyngeal suction will be performed immediately after birth by using a sterile Delee's catheter gently inserted in to the mouth and nose at a depth not more than 5cm, connected to a electrical suction machine. The suction pressure in the machine was adjusted such that, the negative pressure did not exceed 100 mm hg.
- In the **No-suction group (WIPES Group)**, a sterile soft surgical packing towel in the theater is used to wipe away any visible secretions in the mouth, nose and face. If subsequent wipes are needed sterile gauze pieces are used. In babies with profuse secretions, the head is tilted laterally to one side to allow pooling of secretions in the cheek and wiping done.

The newborn dried thoroughly under radiant warmer in the nicu corner at the operation theater and other routine care was given.

#### **4. EXIT CRITERIA**

1. If baby develops bradycardia  $<100$  or apnea or hypotonia during resuscitation that baby will be given gentle electrical suction if needed and bag and mask ventilation and further resuscitation will be done as per NRP 2011 protocol .
2. If the baby on wipes (NO suction group) develops repeated cough or suspected to have airway obstruction after wiping, electrical suction will be used if needed and will be marked as crossing over.

#### **5 .ESTIMATED SAMPLE SIZE FOR A EQUIVALENCY TRAIL**

##### **For Primary Outcome**

- From a previous study, time to reach 92% saturation ( $6.8 \pm 1.8$  in no suction,  $10.2 \pm 3.3$  in suction), the effect size was 3.4 minutes difference between the two groups. We aimed to detect a difference of 2 minutes between both the groups. For 80% power and a standard deviation of 3.3 the calculated sample size is 47/group total (94). Considering 20% loss, 112 patients are required.
- Calculations are based on an online tool at [www. sealedenvelope.com](http://www.sealedenvelope.com) for an equivalency trial.

## **6. RANDOMIZATION AND SEQUENCE GENERATION**

A computerized block randomization sequence was generated with 1:1 allocation and a block size of six.

## **7. ALLOCATION OF CONCEALMENT MECHANISM**

Group selection was determined by assignments from sequentially numbered sealed opaque envelopes opened in the delivery room .

## **8. BLINDING**

Masking of the intervention allocation from the medical personnel within the resuscitation area was not practically possible the person, who data transferred the recordings from the pulseoximeter to the computer and the person/statistician who analyzed the results were blinded.

## **9. IMPLEMENTATION**

The guide generated the Randomisation sequence using an online tool at [www.randomization .com](http://www.randomization.com) in blocks of six .The guide issued the sealed opaque envelopes containing the allocation, to the elective Lscs Theater staff nurse. She issues the covers daily, to the assisting sister at the resuscitation table. The assisting sister or the pediatric Pg opens the cover and reads the intervention to the DM Pg resuscitator.

## 10. PROCEDURE

- Prospective mothers with term gestation, posted for Lscs on the next day are screened, explained about the study and informed consent obtained. Those who gave consent are enrolled. All the deliveries in the period are attended by trained pediatric pgs and the primary investigator or one of the other dm pgs. At the baby corner, both soft sterile packing towels from the elective theater and single use sterile Delees catheter connected to the suction machine are kept ready. Two Pulseoximeter (Masimo radical -7) with reusable wrap type probes are connected to the power supply, the machine switched on and kept ready. The neonatal sensor with Velcro wrap is connected to the rest of the cable of the probe through a detachable adapter. The sensor is detached from the machine, by unlocking this adapter. This is to ensure that the pulseoximeter probe sensor is connected to the neonate first, and then it is connected to the machine for early picking up of signals (Recommended by NRP 2011).
- On delivery of a neonate with inclusion criteria, the nursing sister/pediatric pg assisting resuscitation on that day, opens the randomization cover which was partially teared just before delivery and informs the intervention to the postgraduate. The baby's birth time is noted from the time displayed in the pulseoximeter in 3 digits

(hrs, mints, and seconds) by the sister. Baby positioned in the warmer, and given the intervention, suction or wipe by the investigator.

- During the intervention, the assisting sister or one of the postgraduates attending the resuscitation, wrap a reusable neonatal saturation sensor (MASIMO RADICAL 7) in the right palm of the baby. Sao<sub>2</sub> and heart rate data are recorded upto 15 minutes from the birth time noted in the pulseoximeter. The pulse oximeter was set with an averaging time of 2 seconds and the recordings are stored in the database of the pulseoximeter.(29) The time taken to reach 92 % saturation (primary outcome) is also noted manually in the proforma. The end time of recording for that baby is also noted manually in three digits. (Hrs, Mints, Seconds).
- The baseline data, Apgar scores, are recorded in a prescribed proforma and the follow up was done in postoperative wards. The baby is examined for tachypnea at 30 minutes after birth (before shifting from the theater) and at 6-8 hrs of life and the next day morning 24 hrs by the postpartum pg and assistant professor taking rounds at a leeway of 2-4 hrs.

- The data from the pulseoximeter is transferred to a computer using Masimo -Trend, data transfer software. A data entry person who has no knowledge about the study and who was instructed how to transfer and store the data by the investigator transferred the data. The data transfers itself as an excel sheet.
- The newly posted pediatric postgraduates and the assisting sisters, on their initial 2 days of posting, are educated about the procedure to be done at Lscs theater, and are given mock training at the neonatal ward by the primary investigator.

## **11. Data Management**

- During analysis, Using the time period of recording the individual patient's data is retrieved. From the birth time, The corresponding 1 minute, 2 minute,... upto 15<sup>th</sup> minute value of Sao<sub>2</sub> and pulse rate in the recording is noted and transferred to another excel sheet and used for analysis.

Those outliers due to loosening of probe (time period) which was noted during recording are excluded from the analysis.

- If the Pulseoximeter alarm messages displayed in the excel sheet show low perfusion, low IQ signal, sensor off, ambient light, then the corresponding saturation and pulse rate values are excluded.

- For calculating the proportion of neonates reaching saturation values of 92%, 85% and 95 % saturation, a 30 second averaging to the nearest minute was used to compare between both the groups.
- The primary outcome ( $> 92\%$  sats) if available in the data base is compared with the manually recorded timing. If both the timing correlates with each other that, case and the timing of primary outcome is included for analysis.
- If at least three consecutive 2 second recordings are  $\geq 92\%$ , that time (6<sup>th</sup> second) is taken as the stable time to reach 92% and is used for analysis. Similar criteria is used to identify the time to reach 85% and 95% saturation.

## **12. Statistical Analysis**

All data were entered in Excel 2007 and statistical analysis was performed using the statistical software SPSS 16.0. Data were expressed as frequency, percentages, mean values (with standard deviations), or median values (with Inter Quartile Ranges). Categorical variables were analysed with Chi-square or Fisher's exact test. Continuous variables were analysed with independent samples t-test or Mann-Whitney U test. Results were defined as statistically significant when the *P* value (2-sided) was less than 0.05.



**13. Ethics approval:**

Institutional Review board/Independent Ethical committee,  
Government Rajaji Hospital, Madurai –approved.

Approval reference number 20735/E4/2/2013 date 18/11/2013.

**14. Trial Registration:**

The study is registered in clinical trial registry of India. CTRI  
registration number is REF/2014/01/006385.

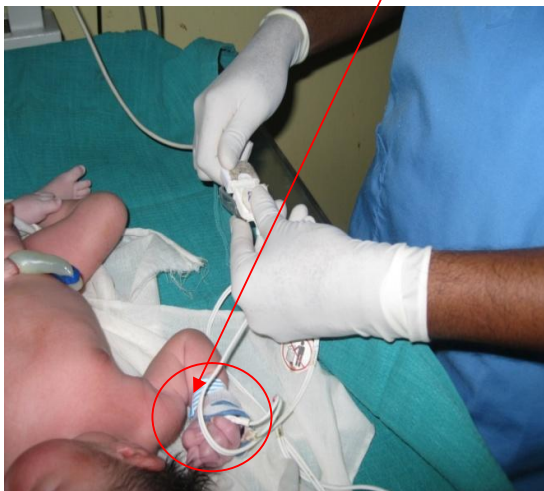
## Resuscitation Corner



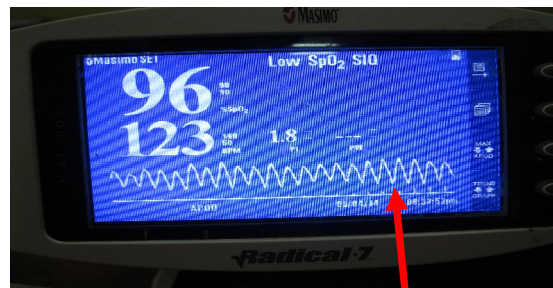
## Randomisation Covers



Connecting the probe to the baby first,  
then to the machine.

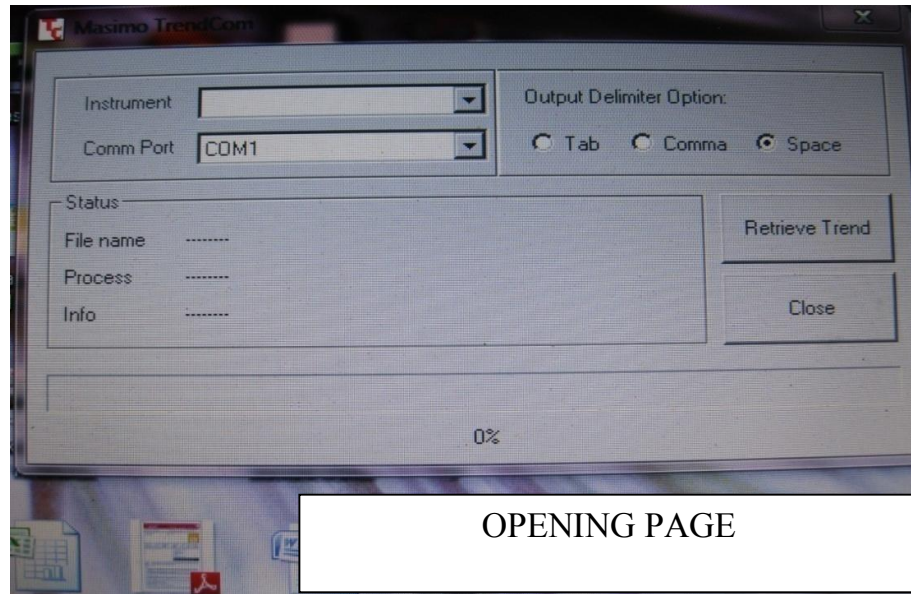


## Pulseoximeter –Masimo Radical 7



Time in Hrs, Mints, Sec

## Trend Software

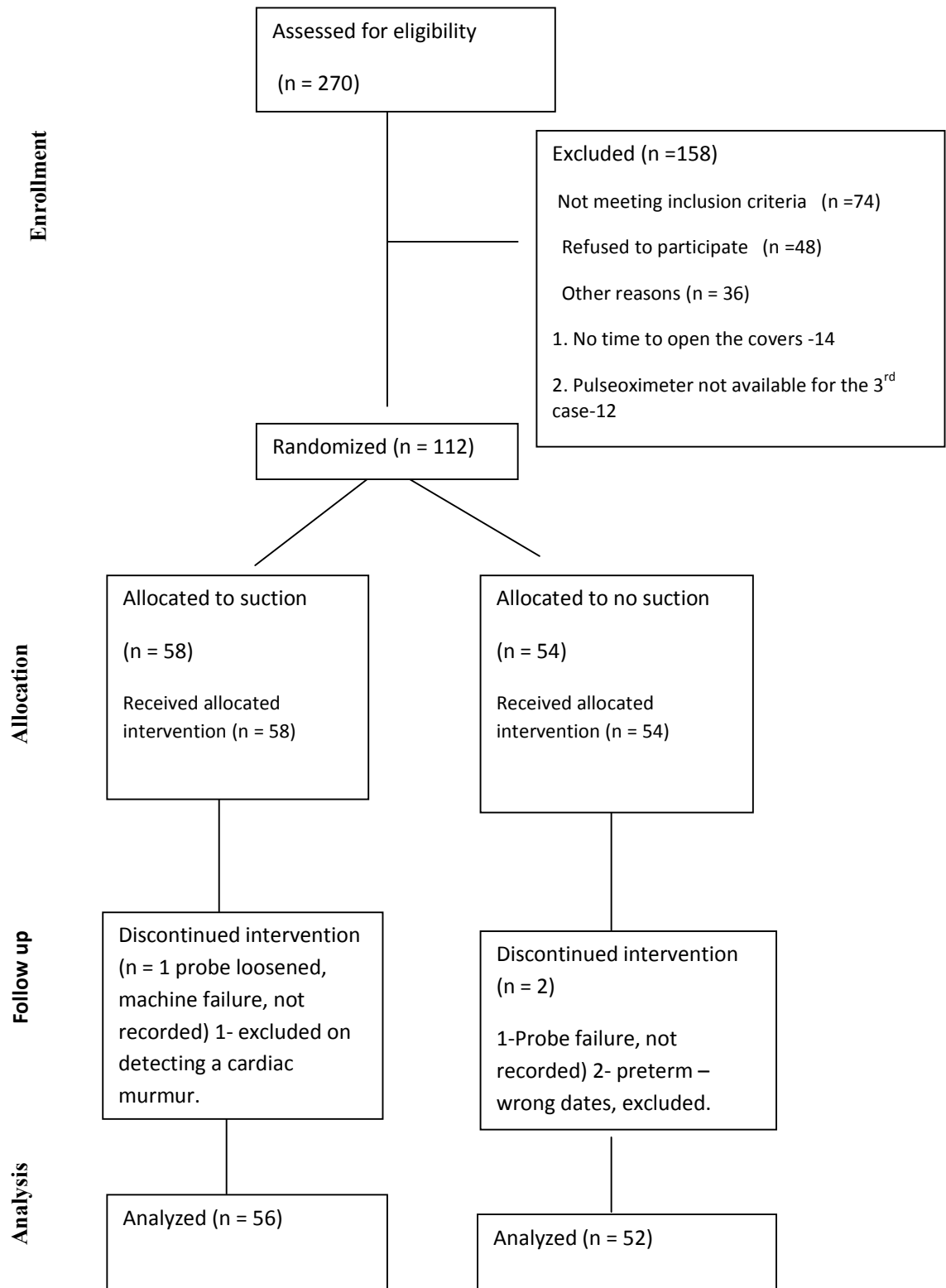


## Data Transferred to Computer as Excel Sheet

The screenshot shows an Excel spreadsheet with data transferred from the Masimo TrendCom software. The spreadsheet has a standard Excel interface with a ribbon at the top containing tabs for 'File', 'Home', 'Insert', 'Formulas', 'Data', 'Review', and 'View'. The 'Home' tab is active, showing various options for font, alignment, and styles. The data is organized into columns labeled A through P. The first column (A) is 'Date', the second (B) is 'Time', and the third (C) is 'SpO2'. The remaining columns (D through P) contain various physiological parameters and alarm status indicators. The data is organized into rows, with the first row (1) being a header row and subsequent rows (2 through 25) containing individual data points. The data is organized into rows, with the first row (1) being a header row and subsequent rows (2 through 25) containing individual data points.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1	Date	Time	SpO2	PR	PI	SpCO	SpMet	PVI	SpHb	SpOC	RESVD	Exception	Exception Labels			
2	12/20/2013	10:46:11	99	147	0.3	0	0	19	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
3	12/20/2013	10:46:13	99	147	0.3	0	0	19	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
4	12/20/2013	10:46:15	99	148	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
5	12/20/2013	10:46:17	99	148	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
6	12/20/2013	10:46:19	99	147	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
7	12/20/2013	10:46:21	99	147	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
8	12/20/2013	10:46:23	99	147	0.3	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
9	12/20/2013	10:46:25	100	147	0.3	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
10	12/20/2013	10:46:27	100	148	0.4	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
11	12/20/2013	10:46:29	100	147	0.4	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
12	12/20/2013	10:46:31	99	148	0.4	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
13	12/20/2013	10:46:33	99	148	0.4	0	0	18	0	0	0	4004003	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
14	12/20/2013	10:46:35	99	148	0.3	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
15	12/20/2013	10:46:37	99	149	0.3	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
16	12/20/2013	10:46:39	99	149	0.3	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
17	12/20/2013	10:46:41	98	149	0.3	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
18	12/20/2013	10:46:43	98	149	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
19	12/20/2013	10:46:45	98	148	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
20	12/20/2013	10:46:47	99	149	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
21	12/20/2013	10:46:49	99	148	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
22	12/20/2013	10:46:51	99	147	0.2	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
23	12/20/2013	10:46:53	100	148	0.3	0	0	18	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
24	12/20/2013	10:46:55	100	147	0.3	0	0	19	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		
25	12/20/2013	10:46:57	100	147	0.3	0	0	19	0	0	0	4004001	(PulseOx) Alarm	(PulseOx) (PI) Low Alar		

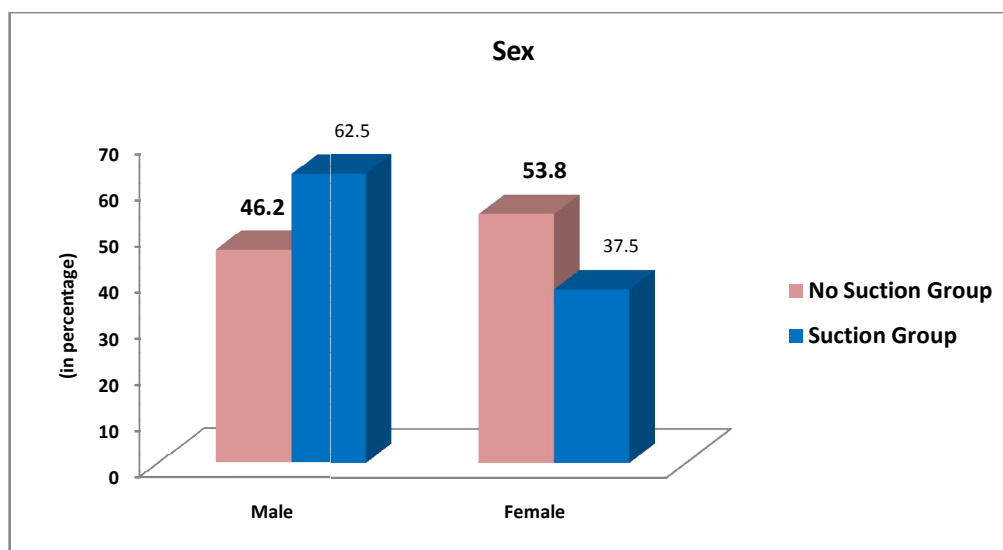
## The flow of participants



## RESULT

**Table 2. Total Number of Neonates & Sex Distribution in Both Groups.**

Sex	No Suction Group		Suction Group	
	No.	%	No.	%
Male	24	46.2	35	62.5
Female	28	53.8	21	37.5
<b>Total</b>	<b>52</b>	100	<b>56</b>	100.0
<b>p - value</b>	0.088			



52 Neonates in the No- Suction group and 56 Neonates in the Suction group were taken for analysis. The sex distribution was not statistically different between both groups.

**Table 3. Indications for Lscs**

Type of Indication	No Suction Group		Suction Group	
	No.	%	No.	%
Prev LSCS	43	82.7	44	78.6
BOH	2	3.8	1	1.8
Oligohydramnios	-	-	1	1.8
Medical Illness	7	13.5	5	8.9
Breech	-		2	3.6
Short stature	-		3	5.4
Total	52	100.0	56	100.0
<b>p - value</b>	0.257			

**Table 4.Mode of Anesthesia**

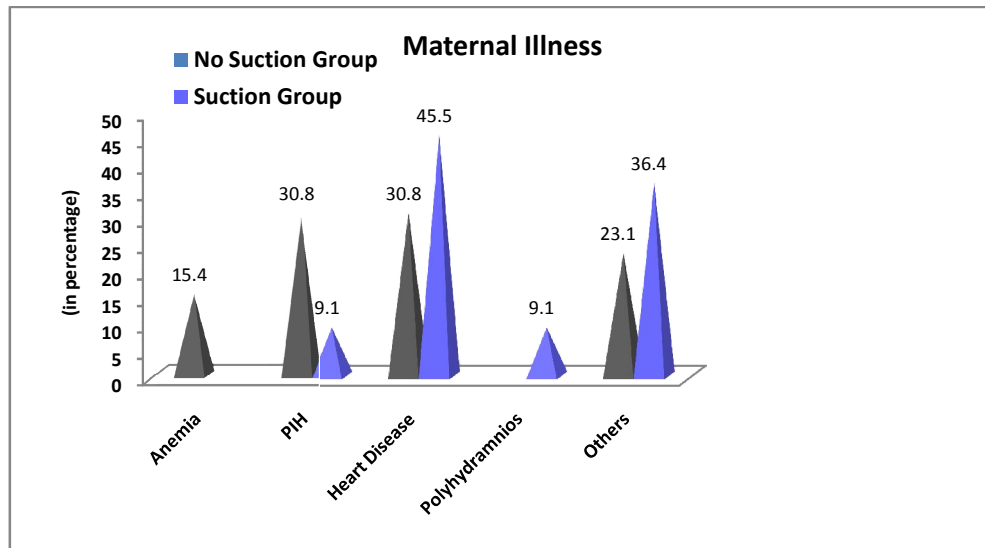
Anesthesia	Group		Total
	No suction	suction	
Spinal	48	53	101
GA	4	3	7
Total	52	56	108
<b>P value</b>	0.709		

Previous cesarean section is the major indication in both the groups. Medical illness in the mother particularly, PIH is the next major indication. There is no statistically significant difference between the two groups, in indication for elective Lscs. There is no significant difference in the mode of anesthesia between both the groups.

**Table 5. Maternal Illness**

Maternal Illness	No Suction Group		Suction Group	
	No.	%	No.	%
Anemia	2	15.4	-	-
PIH	4	30.8	1	9.1
Heart Disease	4	30.8	5	45.5
Polyhydramnios	-	-	1	9.1
Others	3	23.1	4	36.4
Total	13	100.0	11	100.0
p - value	0.295			

(\*Hypothyroidism, Diabetes,)

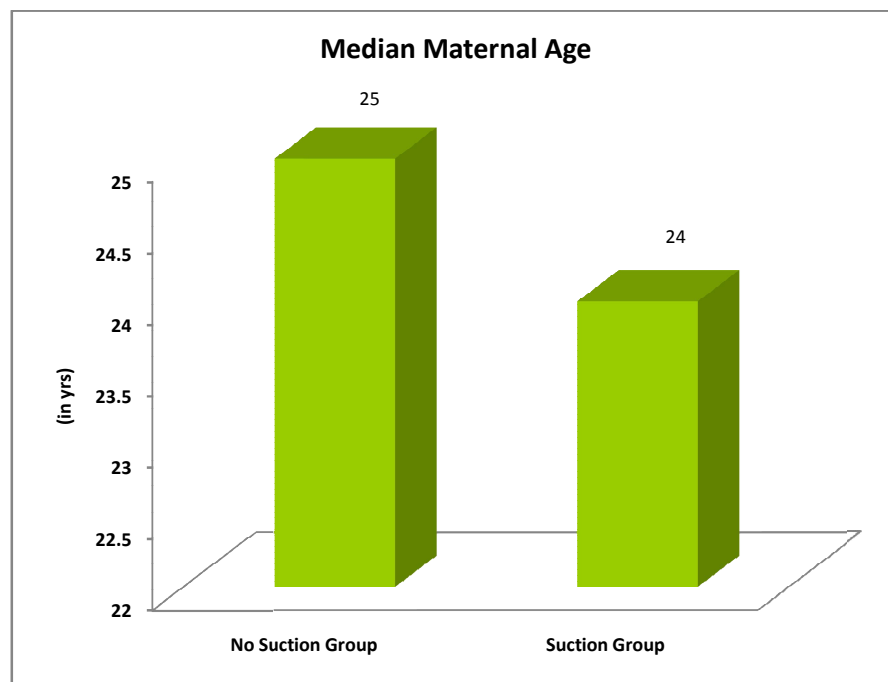


Polyhydramnios was present in 1 case in the suction group. Oligohydramnios was present in both groups with no significant difference. The individual causes of maternal illness are not statistically significant in both groups.

**Table 6. Maternal Age**

<b>Maternal Age (in yrs)</b>	<b>No Suction Group (n=52)</b>	<b>Suction Group (n=56)</b>
Median	25	24
IQR	(24 - 28)	(23 – 26)
<b>P – value</b>	0.020	

The maternal age was statistically different between both the groups.





**Table 7. Baseline Neonatal Characteristics**

<b>Birth Weight (in kg)</b>	<b>No-suction Group (n=52)</b>	<b>Suction Group (n=56)</b>
Median	3.00	2.90
IQR	2.52, 3.20	2.75, 3.10
<b>p – value</b>	0.660	

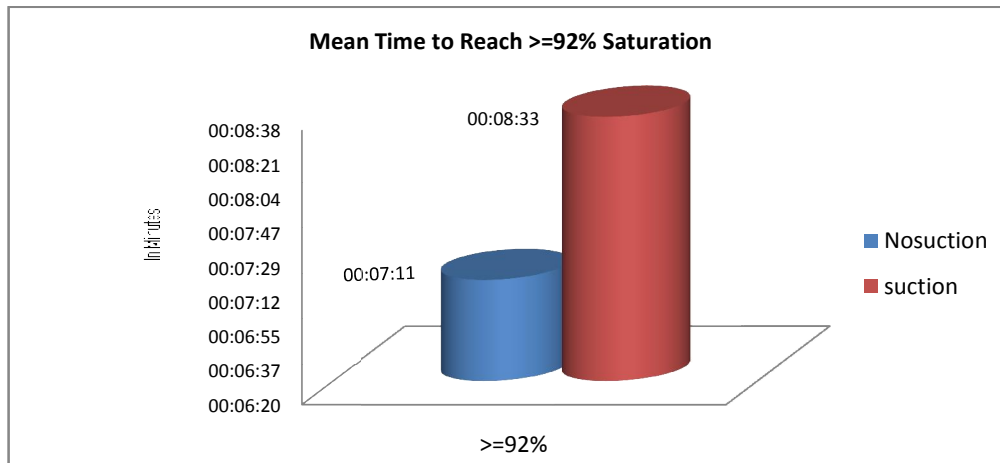
<b>Gestational Age (in weeks)</b>	<b>No-suction Group (n=52)</b>	<b>Suction Group (n=56)</b>
Median	38	38
IQR	38, 38	38, 38
<b>p – value</b>	0.666	

1. The median gestational age was 38 weeks in both the groups and is equally distributed.
2. The median birth weight in No-suction group and suction didn't differ significantly.

**Table 8. Primary Outcome**

**Median time taken to Reach 92% saturation**

<b>92% Oxygen Saturation</b>	<b>No-suction Group (n=52)</b>	<b>Suction Group (n=56)</b>
MEDIAN (Minutes: seconds)	07:06	08:18
IQR	(04:41, 09:17)	(06:44, 10:01)
<b>P - value</b>	<b>0.009</b>	



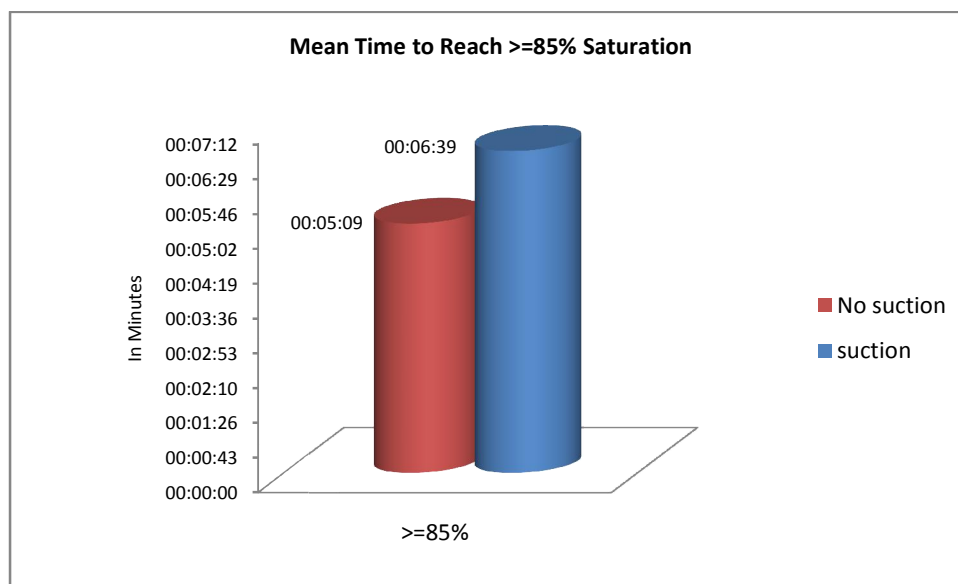
The Median time to reach 92% saturation is 7 minutes 6 seconds in the No- suction group and 8 minutes 18 seconds in the suction group. No - suction group took significantly lesser time to attain saturation levels >92% than suction group. Mean values are 7 min11sec in the no suction group and 8min33 sec in the suction group.

## SECONDARY OUTCOMES

**Table 9. Median time taken to 85% saturation**

<b>85% Oxygen Saturation</b>	<b>No-suction Group (n=52)</b>	<b>Suction Group (n=56)</b>
MEDIAN (minutes: seconds)	<b>5:06</b>	<b>6:17</b>
IQR (minutes: seconds)	(3:21, 5:09)	(6:25, 8:24)
<b>p – value</b>	0.001	

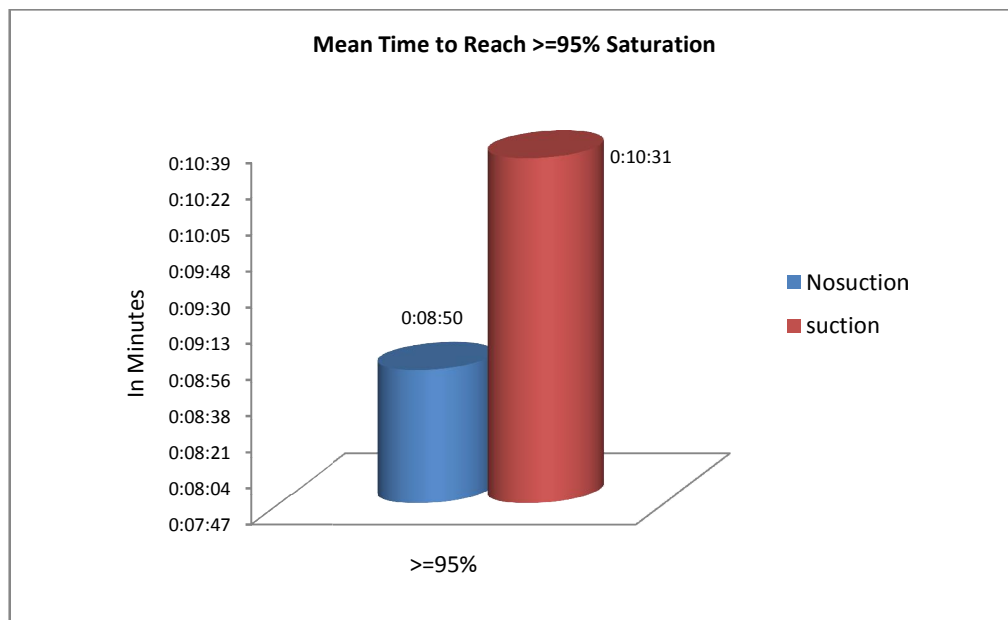
The median time to reach 85% saturation is 5 minutes 6 seconds, is lesser when compared to suction group (6 minutes, seventeen seconds). This difference is statistically significant.



**Table 10. Median time taken to 95% saturation**

<b>95% Oxygen Saturation</b>	<b>No-suction Group (n=52)</b>	<b>Suction Group (n=56)</b>
MEDIAN (minutes, seconds)	8:42	10:26
IQR (minutes: seconds)	(5:59,10:56)	(08:14,12:41)
<b>p – value</b>	0.003	

The Median duration to reach 95% saturation is 8 minutes 42 sec in the No-suction group is earlier than the suction group. (10 minute 26 seconds). This difference is statistically significant.



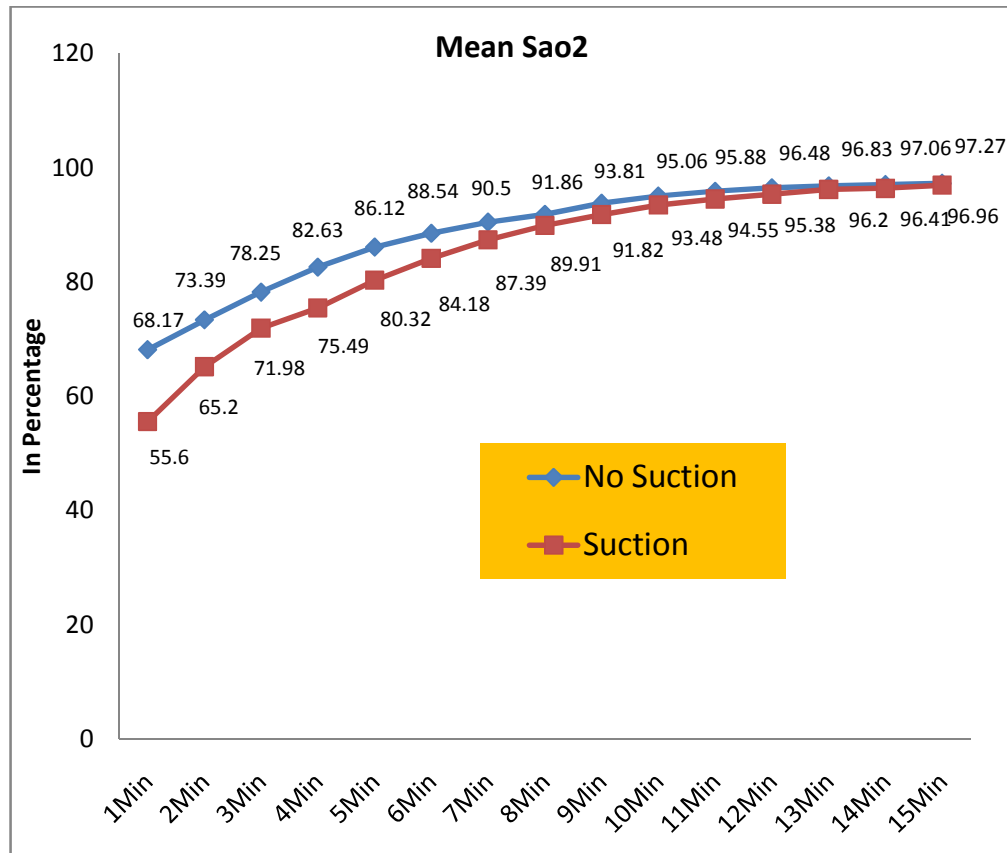
**Table 11. Minute by Minute Comparison of Mean Saturation**

**Minute to Minute Comparison of Mean Saturation**

Minute	NO SUCTION			SUCTION			P VALUE
	N	Mean	Std.Deviation	N	Mean	Std.Deviation	
1M	12	68.17	7.51	5	55.60	17.50	0.05
2M	46	73.39	7.91	46	65.20	12.51	<b>0.000</b>
3M	51	78.25	7.33	54	71.98	9.42	<b>0.000</b>
4M	52	82.63	7.11	55	75.49	11.05	<b>0.000</b>
5M	52	86.12	6.65	56	80.32	9.33	<b>0.000</b>
6M	52	88.54	6.07	56	84.18	7.95	<b>0.002</b>
7M	52	90.50	5.23	56	87.39	6.75	<b>0.009</b>
8M	50	91.86	4.79	56	89.91	5.46	0.055
9M	52	93.81	3.78	56	91.82	4.70	<b>0.018</b>
10M	52	95.06	3.11	56	93.48	3.84	<b>0.022</b>
11M	52	95.88	2.56	56	94.55	3.29	<b>0.022</b>
12M	52	96.48	2.16	56	95.38	2.78	<b>0.024</b>
13M	52	96.83	1.69	56	96.20	2.50	0.13
14M	52	97.06	1.42	56	96.41	1.65	<b>0.031</b>
15M	52	97.27	1.42	56	96.96	1.32	0.143

**P value (1-14 minutes) - T test for independent samples, 15th min-  
mannwhitney test.**

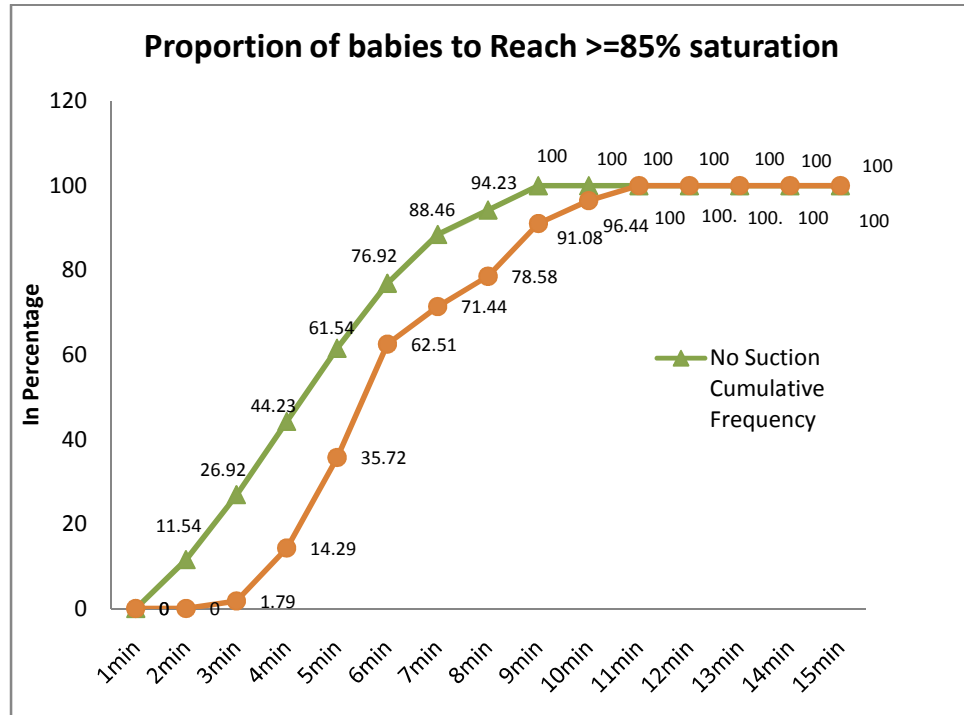
The mean saturation levels are significantly more in the No-suction group at 2 to 7 minutes after birth, then from 9 minutes to 12 minutes and at 14 minutes. This difference is statistically significant.



**Table 12. Proportion of Babies reaching  $\geq 85\%$**

	<b>NO-SUCTION % (n=52)</b>	<b>SUCTION % (n=56)</b>	<b>P Value</b>
1min	0	0	
2min	11.54	0	0.01
3min	26.92	1.79	0.01
4min	44.23	14.29	0.482
5min	61.54	35.72	0.588
6min	76.92	62.51	0.148
7min	88.46	71.44	0.654
8min	94.23	78.58	1
9min	100	91.08	0.323
10min	100	96.44	0.244
11min	100	100	0.496

Cumulative frequency percentage is shown in each group. 30 second averaging time is used to calculate the proportion of babies with saturation  $\geq 85\%$  in each minute.



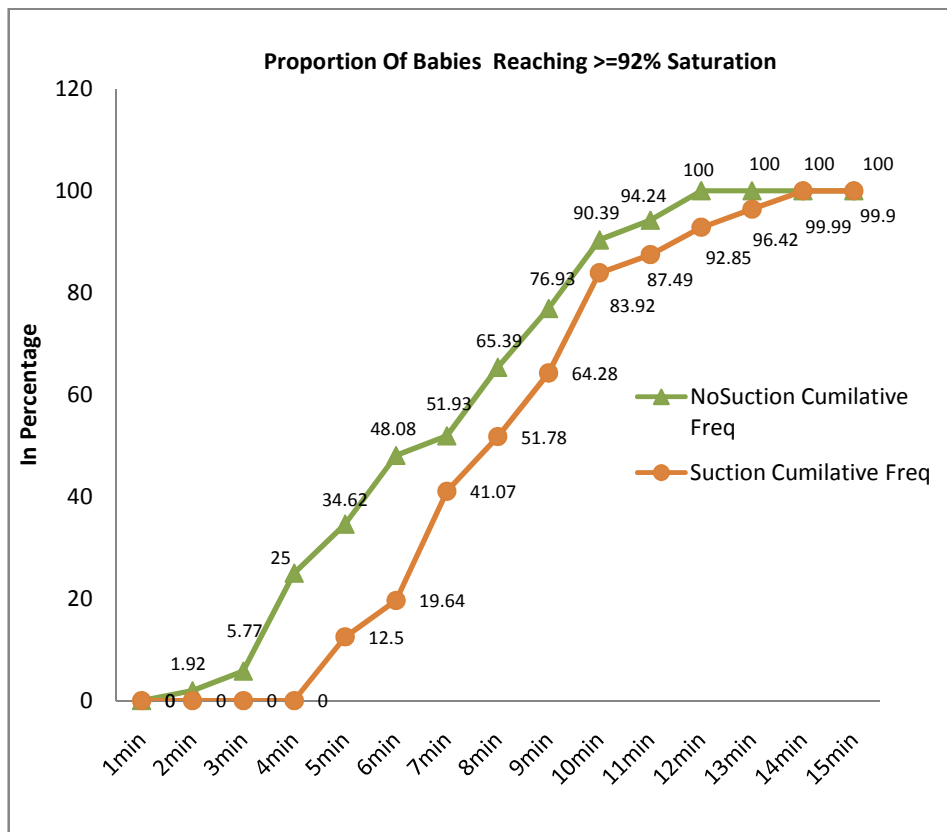
The Proportion of neonates reaching  $\geq 85\%$  are statistically significant at 2nd and 3<sup>rd</sup> minutes after birth with higher proportion in the No-suction (Wipes) group.



**Table 13. Proportion of Babies Reaching  $\geq 92\%$**

	<b>NO-SUCTION % (n=52)</b>	<b>SUCTION % (n=56)</b>	<b>P Value</b>
1min	0	0	0
2min	1.92	0	0.481
3min	5.77	0	0.229
4min	25	0	0.0004
5min	34.62	12.5	0.633
6min	48.08	19.64	0.347
7min	51.93	41.07	0.008
8min	65.39	51.78	0.661
9min	76.93	64.28	0.878
10min	90.39	83.92	0.389
11min	94.24	87.49	1
12min	100.01	92.85	1
13min	100.01	96.42	0.496
14min	100.01	99.99	0.496

Statistically Significant higher proportion of neonates reached  $\geq 92\%$  saturation at 4<sup>th</sup> and 7<sup>th</sup> minute in No-suction group compared to suction group.

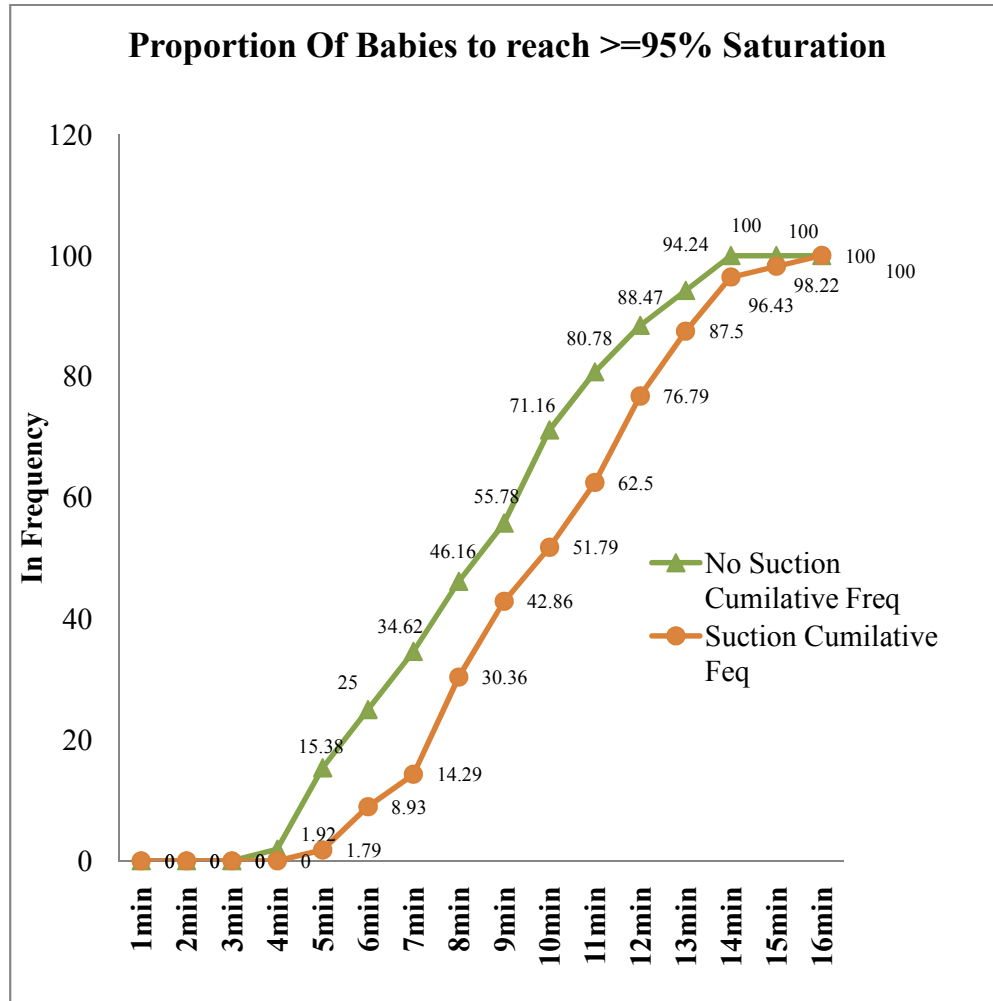


100% of the Neonates in the no suction group reached  $\geq 92\%$  saturation at 12 minute while the same is reached at 14 minutes by the suction group.

**Table 14. Proportion of Babies Reaching  $\geq 95\%$**

	<b>NO SUCTION % (n=52)</b>	<b>SUCTION % (n=56)</b>	<b>P Value</b>
1min	0	0	0
2min	0	0	0
3min	0	0	0
4min	1.92	0	0.481
5min	15.38	1.79	<b>0.027</b>
6min	25	8.93	0.735
7min	34.62	14.29	0.477
8min	46.16	30.36	0.496
9min	55.78	42.86	0.633
10min	71.16	51.79	0.302
11min	80.78	62.5	0.85
12min	88.47	76.79	0.363
13min	94.24	87.5	0.491
14min	100	96.43	0.717
15min	100	98.22	1
16 min	100	100	1

Statistically Significant higher proportion of neonates reached  $\geq 95\%$  saturation at 5<sup>th</sup> minute in the No-suction group compared to suction group.



The slowest Neonate in the no suction group took 14 minutes to reach  $\geq 95\%$  saturation and in the suction group it took 16 minutes to reach  $\geq 95\%$  saturation.

**Table 15. Comparison of Mean Pulse Rate Minute by Minute**

	PULSE RATE						P VALUE
	NO-SUCTION			SUCTION			
MINUTE	N	Mean	Std. Deviation	N	Mean	Std. Deviation	
1 MIN	10	115.1	8.80	5	122.8	11.56	.172
2 MIN	30	134.5	13.22	25	136.8	15.11	.544
3 MIN	38	145.4	10.80	36	149.9	13.76	.121
4 MIN	48	155.1	10.95	44	149.4	15.54	.045
5 MIN	52	162.2	9.36	53	155.2	14.88	.005
6 MIN	52	156.6	17.37	55	154.7	13.96	.532
7 MIN	51	155.7	16.80	55	155.3	12.88	.892
8 MIN	50	157.6	16.28	54	155.7	13.18	.518
9 MIN	52	156.8	15.39	55	154.1	13.49	.327
10 MIN	51	154.8	14.59	56	152.8	14.50	.467
11 MIN	52	154.8	15.18	56	151.3	15.80	.236
12 MIN	52	151.4	16.26	56	151.8	14.68	.874
13 MIN	52	151.9	15.39	56	153.1	14.29	.669
14 MIN	52	154.3	14.29	56	153.1	13.56	.646
15 MIN	51	154.5	13.21	51	150.9	12.61	.164

The No-suction group had significantly high mean pulse rate at 4 and 5 minutes of life compared to suction group. In the Rest of the 15 minutes mean pulse rate was not significantly different between both the groups.

## OTHER SECONDARY OUTCOMES

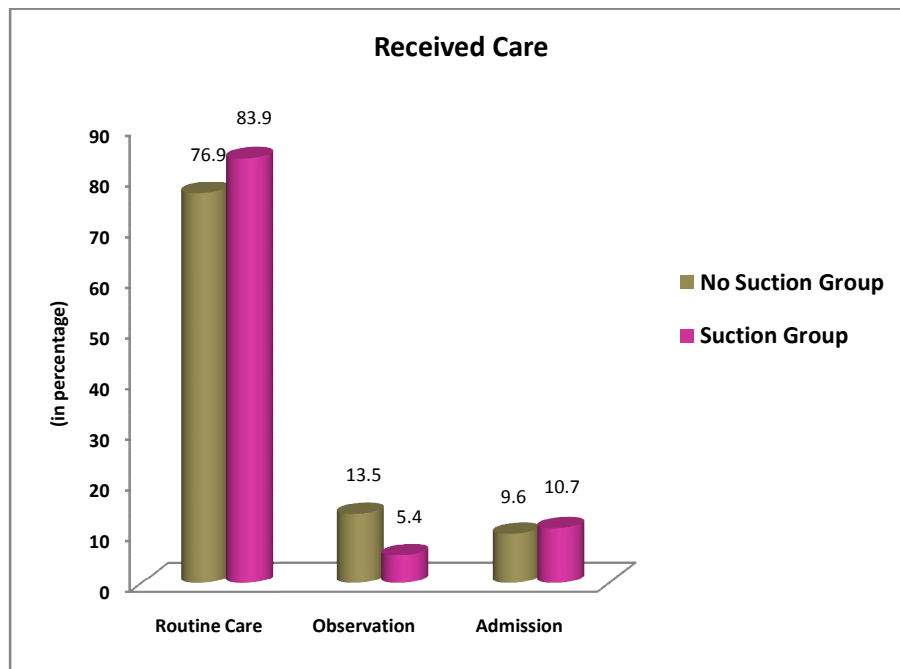
**Table 16. APGAR Score at 5 Minutes**

	<b>N</b>	<b>MEAN</b>	<b>STD DEV</b>
No-suction	52	8.87	0.34
Suction	56	8.82	0.39
P VALUE		0.535	

All the babies had Apgar score  $\geq 8$  at 5 minutes. The mean scores are not statistically different between both the groups.

**Table 17. Number of babies admitted**

Received Care	No-suction Group		Suction Group	
	No.	%	No.	%
Routine Care	40	76.9	47	83.9
Observation	7	13.5	3	5.4
Admission	5	9.6	6	10.7
Total	52	100.0	56	100.0
<b>p - value</b>	0.348			



There is no significant difference in the number of babies admitted.

**Table 18. Duration of Stay in admitted babies.**

<b>Duration of Stay (in days)</b>	<b>No-suction Group (n=5)</b>	<b>Suction Group (n=6)</b>
Mean(min,max)	4.4(3,7)	3.83(3,5)
SD	1.67	0.75
<b>p – value</b>	0.588	

There is no significant difference in the duration of stay between both the groups.

**Table 19. Causes of Admission**

	<b>NO-SUCTION (n=5)</b>	<b>SUCTION (n=6)</b>
BOH	1	1
RH INCOMPATABILITY	2	1
INFANT OF DIABETIC MOTHER	1	2
IUGR,LBW<2 KG	1	1
HYOPHTHYROID MOTHER		1

5 babies in the No-suction group and 6 babies in the suction group are admitted for reasons not related to the trial.



### **Neonates under Observation Care**

7 neonates were kept for observation at newborn ward in the No-suction group and 3 babies taken for observation in the suction group. But this difference is not statistically significant. These neonates were observed for 2 hours.

### **Other Outcomes**

None of the babies developed tachypnea  $> 60$  respiratory rate on follow up in the first 24 hour.

There is no mortality within 28 days of life in either arm of the trial.

## **DISCUSSION**

Our study is a single center, randomized control trial addressing routine suction or wiping at birth. About 270 elective Lscs are done over 4months. This constitutes 7.5% of Total deliveries. In a multicenter study by ICMR an uprising, 44% elective Lscs deliveries in our country has raised concerns.(30) Other centers from developed countries report 30% of total deliveries as caesarean section(31). In a similar study, done by Gungor and associates, the total number of caesarean deliveries was not mentioned.

The baseline maternal characteristics were similar in both the groups, except for maternal age in our study. The median maternal age is 25 in the no- suction group and 24 in the suction group and this difference has no clinical relevance.

The most common indication for elective caesarean section in our study was a previous caesarean section. Similar finding was reported in other studies also.((31))

Among the 270 elective Lscs babies, about 112 babies are randomized. 58 babies received suction and 54 wiping with a towel. Finally 52 Neonates in the no suction group and 56 Neonates in the suction group were included for analysis. About 8 Neonates (7.1%) drop out occurred after

Randomisation in our study. 4 % dropouts was reported after randomization in a large RCT by Kelleher(28) and associates.

The Primary outcome we measured in the present study is, the time taken for 92% saturation. This is based on previous trials.(24,25,27) reporting that this is the lowest acceptable saturation value in term neonates at birth. In an another trial, the mean respiratory rate in the first 24 hrs was used as the primary outcome.(28) To assess the important outcomes like mortality and morbidity between the two groups, our study design does not have adequate power to assess these outcomes. Considering the wide variability in respiratory rate and the concerns like hypoxia and bradycardia reported in some studies, we thought pulseoximeter assessment of SaO<sub>2</sub> and heart rate will be a better outcome measure.

We have used the Right palm of the neonate for recording (preductal saturation). Fixing the probe over the middle finger was used in a similar study by Gungor et al.(27)

In Waltman study, the sensor was placed on the hand, right or left hand was not mentioned.(25) In that study, ECG recording was also used to check the heart rates. Because of the availability of newer pulseoximeters with motion artifact technology, the time needed to place the ECG

electrodes, and the motion artifacts in ECG due to limb movement, we did not choose electrocardiogram for recording.

The Pulse oximeter used in 2005 by Gungor and associates was system III, infant monitor, Air shields, USA) for monitoring. Measurements were documented minutes by minutes. But in our study, we used Masimo radical – 7, newer generation pulseoximeter for recording pulse rate and SaO<sub>2</sub> and the data was transferred to a computer for analysis. The pulseoximeter- Masimo radical -7 used in our study has an accuracy of 70-100% for saturation. Neonatal probes has  $\pm 3$  digits accuracy for recording saturation with or without motion and  $\pm 3$  digits accuracy for heart rate without motion and  $\pm 5$  digits for heart rate can occur during motion. (29) In similar trials, by Waltman and Carassco, (24, 25) the pulseoximeter used and the method of recording was not known.

In our protocol, we choose 15 minutes recording based on previous studies reporting an average 12 -13 minutes stabilization time. But in our study, one Neonate took more than 15 minutes (16 minute) to reach >95% saturation. After implementing the criteria as mentioned in the data management, totally 1507 minute saturation values are taken for analysis in our study.

The median duration taken by No-suction (wipes group) to reach 92% is 7 minutes 6 seconds in the no suction and 8 minutes 18 seconds in the suction group. Lesser time taken by no suction group compared to suction group is statistically significant. The mean time taken to reach a saturation of 92% is also lesser (7 minutes 11 seconds  $\pm$  2.39 S.D) in the No suction group compared to 8 minutes 33 seconds  $\pm$  2.19 S.D in the suction group. Although our trial showed earlier oxygenation in the no suction (wipes) group, our trial was planned for equivalency only.

A Posthoc superiority analysis showed that for the primary outcome, the mean time difference of 1 minute 22 seconds between both the groups, and a standard deviation of 2.39, the current sample size has only 70 % power for superiority analysis.

In a similar study, significantly lesser time taken by no suction group for oxygenation is noted by Carassco et al. (24, 25) In that pilot study the mean minute to 92% rate was  $6.8 \pm 1.8$  in the no suction group and the suction group took  $10.2 \pm 3.3$  minutes.

In our study the time taken to reach 85% saturation and 95% saturation, is also significantly lesser in the no- suction group, compared to suction group.

The No suction group took 1minute lesser median time than the suction group to reach 85%, and 1minute 13 seconds lesser to reach 92% and 1 minute 30 seconds lesser to reach 95% saturation.

This finding is similar to other studies Gungor et al, Carassco et al reporting that no suction group took significantly lesser time to reach 85%, 92 % and 95% saturation than suction group.

The Median time took by the no suction group and suction group to reach 85% saturation are 5 Minutes 6sec (IQR [03:2, 05:09]) and 6minutes 17 Seconds IQR [(06:25, 08:24)] respectively in our study.

Other studies reported mean time of 5 minutes  $\pm 1.2$  for no suction group and  $8.2 \pm 3.3$  minutes for suction group to reach 86% rates (Carassco)

In another study by Waltman (24, 25) comparing No Suction versus Bulb suction in 20 neonates, at the end of 20 minutes, SPO<sub>2</sub> levels were approximately 97% in the suction group and 92% in the no suction group.

In our study the Mean Saturation values at 3,5,10, minutes of life are higher in the No suction group than the suction group. The mean saturation values are 78.2, 86.1, 95.06, and 97.27 in the no suction group whereas it is 71.98, 80.32, 93.48, and 96.96 in the suction group at 3,5,10, 15 minutes of life respectively.

At 15<sup>th</sup> minute the mean saturation levels are not significantly different between both groups.

The trend of mean saturation values are significantly higher in the no suction group from 2 to 6minutes of life, then from 7 to 12 and at 14 minutes after birth compared to suction group in our study.

Similarly, Waltman reported at 5minutes the no suction group had higher saturation level. But in contrast to our group, the same study reported higher saturation level at 10 and 15minutes of life in the suction group than the No Suction group.

Similar to our study, in a RCT by Gungor et al, a significant higher saturation levels at 3, 5 and 6minutes in the No Suction group than the Suction group is observed. In that study, saturation values after 6minutes of life in the No suction group are not available.

In our study the proportion of babies reaching 92% saturation are also significantly more in the no suction group than the suction group at four and seventh minute after birth. Similarly the more number of babies in the no suction group reached 85% saturation at 2<sup>nd</sup> and 3<sup>rd</sup> minutes and at 5<sup>th</sup> minute significantly more number of neonates in the no suction group reached a saturation  $\geq 95\%$ .

Similar to our study, more number of babies reached 92% saturation (100%) at 6 minutes of life in the no- suction group in Gungor study.(27)

In our study ,the slowest neonate in the no-suction group took 9 minute, 12 minute, 14 minute to reach 85%, 92%, 95% respectively whereas same saturation levels are reached at 11,14,16 minute respectively in the suction group.

In Gungor study, 100% of the neonates reached 92% saturation at 6 minutes in the no suction group and 11 minutes in the suction group. In contrast, in our study, 100% of the neonates reached 92% saturation at 12 and 14 minutes respectively.

### **Heart Rate:**

In our study none of the neonates developed bradycardia. There is a significantly higher mean heart rate at 4<sup>th</sup> and 5<sup>th</sup> minute after birth in the No suction group compared to the suction group.

In contrast few other studies reported bradycardia in the Suction group. (23) But in a RCT by Gungor et al, they reported lower mean heart rates in the No-Suction group. But the heart rates were within the normal limits in both the groups.



Dawson & associates, in their pulseoximeter study on delivery room found that the mean heart rate after birth starts rising at 3 and 5 minutes after birth and stabilises thereafter in normal term neonates. We also noted a trend of raising mean heart rates in the first five minutes after birth, in both the groups. This raise may be lesser in the suction group at 4 and 5 minutes leading to significantly lower mean heart rates at these minutes.

### **Other Outcomes:**

There is no mortality in either arm and there is no significant difference in respiratory distress noted between both the groups.

5 babies in the no suction group and 6 babies in the suction group were admitted for reasons not related to the trial. The duration of stay is also not significantly different between the groups. The minimum stay was 3 days and the maximum is for one baby in the suction group who was treated for Rh incompatibility with phototherapy for 7 days.

Other babies admitted in both the groups had other indications like hypothyroidism, Rh incompatibility & IUGR. Of the 10 babies taken for observation in the ward, 7 babies are from the no suction group and 3 babies are in the suction group. Seven babies in the no suction group found to have mild retraction at birth, respiratory rate <60, and good cry, were taken for observation in the neonatal ward and the distress resolved within 1 hour.

One neonate in the suction group had  $<95\%$  saturation at 15 minutes, who subsequently improved after supplemental oxygen and reached  $\text{SaO}_2 >95\%$  at 16 minutes. That Baby was kept in the ward to watch for further fluctuation in saturation. After 1 hour observation and convincing examination, baby was sent back to postoperative ward. At the start of the study, more number of neonates was taken for observation in the no suction group since wiping is not a routine practice in our hospital. They might have been taken for observation to ensure safety of the babies and after convincing repeat clinical examination, saturation recording, and trial expressed breast milk feeds at ward, the neonates were sent for routine care. Although the number of babies taken for observation is more in the no-suction arm, this difference is not statistically significant.

The APGAR scores are not significantly different between both the groups. The mean APGAR was 8.87 in the Nosuction group and 8.82 in the suction group. None of the babies had significant feeding difficulties in both the groups. None of the babies developed significant tachypnea in the next 24 hours.

Similar to our study other studies by Carassco, Gungor et al (24,26, 27) did not report mortality, or respiratory distress or difference in admission rate between both the groups.

Kelleher (28) reported 18% of the wipe group (no suction) and 12% of the bulb suction group required admission in their study, with no statistically significant difference.

None of the baby required additional resuscitation in our study.

In Contrast, in Kelleher study, 10% of the wipe group and 7% in the suction group required advanced resuscitation. This is probably because of the broad inclusion criteria in their study including a population of late preterm, meconium stained vigorous babies, as well as both vaginal and caesarean deliveries. Also our study includes neonates cried at birth and hence those neonates depressed or asphyxiated at birth would have been excluded.

## CONCLUSIONS

1. Wiping with a sterile towel is equally efficacious with suctioning using a catheter in term neonates born with clear liquor in attaining oxygenation.
2. The time to reach 92%, 85%, 95% saturation levels are significantly lesser in the no suction/wipes group compared to the suction group.
3. The mean saturation levels are significantly higher in the no suction group from 2 to 6 minutes, 9 to 12 minutes and at 14<sup>th</sup> minute.
4. The proportion of neonates reaching saturation of 85%, 92% and 95% are significantly higher in the no suction group in the early minutes (2, 3, 4, 5 and 7 respectively) after birth.
5. Significantly higher mean heart rates are present in the no suction group at 4<sup>th</sup> and 5<sup>th</sup> minute of life.
6. These findings show that routine suction does not have any advantage in the oxygenation at birth, in the present study population.
7. Our study support the Recent NRP recommendation of routine suction is not necessary at birth.
8. Also we don't find any significant bradycardia or adverse effects with a gentle electrical suction in the group of term vigorous elective Lscs, non meconium stained neonates.

## **STRENGTHS**

1. Our study is an adequately powered randomised controlled trial for the primary and most of the secondary outcomes.
2. Presence of multiple resuscitators in the present study mimics real life situations and this gives strength to the finding.
3. The outcome, saturation and heart rate are recorded by the machine, and direct data transfer to the computer avoided observer bias in recording.
4. Blinding the data entry person and statistician analysing the group avoided other biases.

## **LIMITATIONS**

1. The study is restricted to a group of neonates who are term, born elective Lscs, cried at birth and non meconium stained.
2. The study is not done in the other higher risk situations like emergency Lscs, vaginal delivery, late preterm and preterm infants and neonates born with meconium stained liquor. The role of wiping with a cloth compared to suction in these groups are not known.
3. We set a two second averaging time in the pulse oximeter for the present study. Whether using an 8 second averaging time will be more accurate is not known.
4. We used a reusable sensor. Using a disposable sensor for each baby is often impractical and costly in a government hospital in India. But such sensor whether they would remain in place for long time and give better signal is a question.
5. We had less number of recordings in the initial 3minutes of life due to the time taken for shifting the baby and time to place the probe and to get the signal.
6. Also in our study, since have we used only two pulseoximeters for study, multiple deliveries occurring at the same time or within 15 minutes of recording, could not be recorded, this unavoidably leads to some sample loss.

7. Separate resuscitation teams for research and for routine resuscitation care is not feasible in our unit and we feel in most Indian government institutes. Hence we feel in subsequent studies two separate teams, if feasible, is a better option.

## **RECOMMENDATIONS**

1. In Term elective LSCS babies, with clear liquor, who cried at birth wiping with a sterile cloth can be used for routine care. Suction can be reserved for more obvious obstruction.
2. Similar trials in other high risk neonates, like preterm, meconium stained liquor are recommended.



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## ANNEXURE 1

**PROFORMA**

**Date:**

<b>Pulseoximeter</b>						
( Tick)	R1	R2	R3	<b>Group</b>	<b>Suction</b>	<b>No suction</b>
				<b>(Tick)</b>		

<b>Name</b>		Sex: Male / Female	I.P Number
Fathers Name		OG Unit	Place
DOB:	Birth Weight :		Gestational Age :
TIMEOFBIRTH:	Group :		

**Maternal Parameters**

Maternal Age :	Gravida , Para , Live , Abortion	<b>LMP ;</b>  <b>EDD;</b>	
Oligohydramnios,Polyhydramnios	Fetal heart rate monitoring (distress, bradycardia)	Amnioinfusion  Y/N	BLOOD GROUP & TYPE

<b>Meternal Illness</b> (Tick )DM	PIH	ECCLAMPSIA	HEART DISEASE
HELLP SYNDROME	JAUNDICE	TORCH INFECTION	CHORIOAMNIONITIS

CHICKENPOX	APH/Plac Previa		<b>NIL</b>

<b>ANSCAN:</b>	GEST AGE;
<b>DATE</b>	LIQUOR
	ANOMALIES,
	DOPPLER

## RESUCITATION RECORD

### Intrapartum Events

Mode of Delivery	Elec.LSCS
Inadication for LSCS	
Fetal Distress - Y/N	CTG (Normal /Abnormal /Not done )

**(MENTION TIME IN 3 DIGITS ) (EG; 9:40:24)**

Birth Time			
Probe placed time			
time	<b>Sao2</b>	<b>Heart rate</b>	<b>Apgar</b>
1 Minute			
5 Minute			



10 Minute			
15 Minute			
End Time			
Time to Reach 92% sao2			

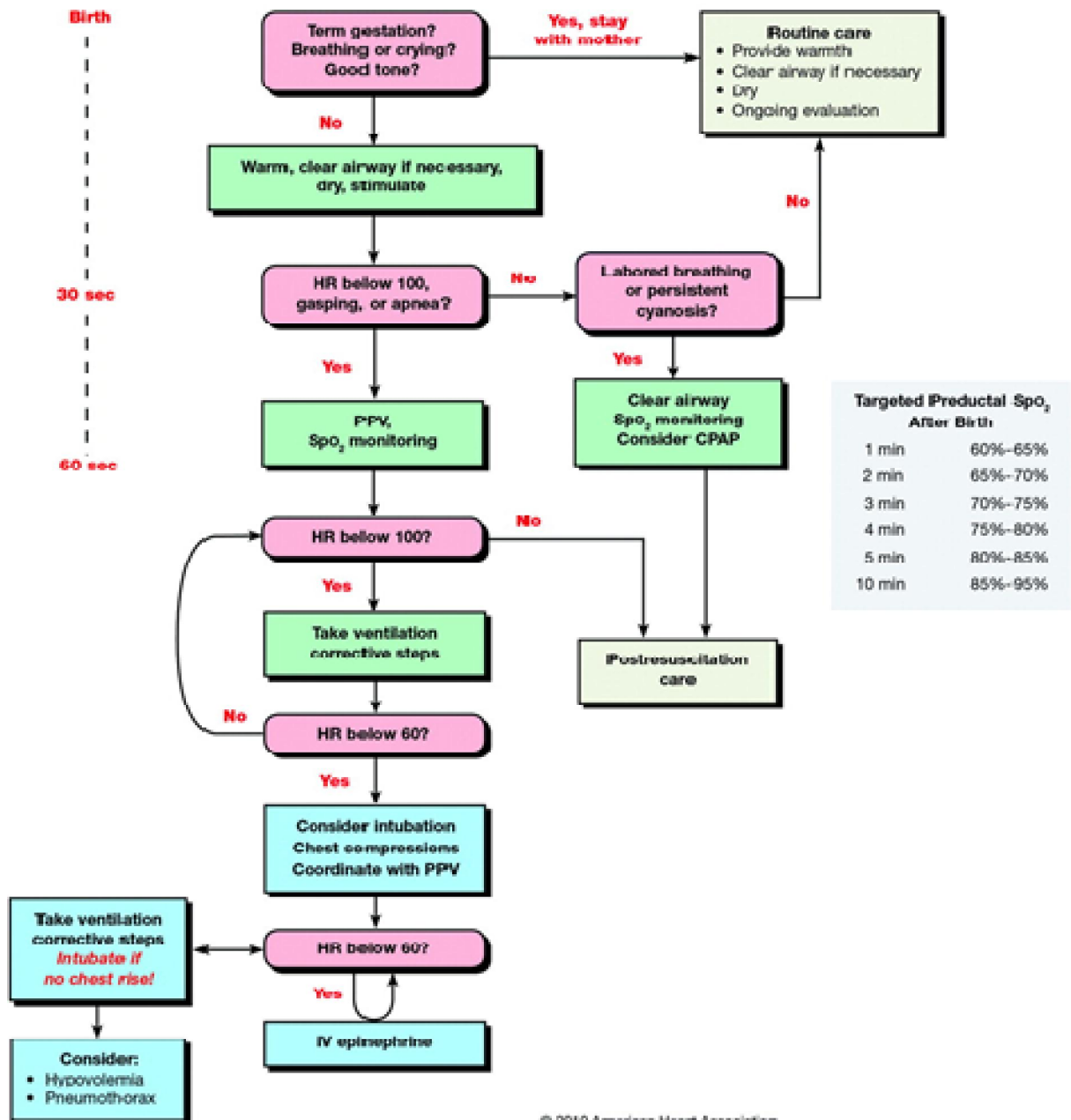
	Tick	Duration
Need for PPV		
Need for Chest Compression		
Need & Time of Intubation		
Need for Adrenaline		

**TICK**

ADMISSION	OBSERVATION	RQUTINE CARE
-----------	-------------	--------------

## ANNEXURE 2 – NRP PROTOCOL 2011 GUIDELINES

### Newborn Resuscitation



#### **ANNEXURE -4 (CODE SHEET)**

GROUP	-	1. No Suction 2. Suction
SEX	-	1. Male 2. Female
INDTYPE	-	1. Prev LSCS 2. BOH 3. Oligohydramnios 4. Medical Illness 5. Breech 6. Tailed Induction 7. Short
RECCARE	-	1. Routine care 2. Observation 3. Admission
MILL	-	1. Anemia 2. PIH 3. Heart Disease 4. DM 5. Polyhydramnios 6. Others

Anesthesia

- 1- Spinal
- 2- GA.

Sao21m-

Saturation at 1minute. Similarly sao2 2M..... Sao2 15m.(15 minute).

PR\_1

PULSE rate at 1 minute.

Similary PR\_2.....PR\_15 is pulse rate at 15 minute.

The Tamil Nadu Dr. M.G.R. Medic...Medical - DUE 24-Apr-2014

OriginalityGradeMarkPeerMark

Routine suction versus nosuction in term neonates born elective lscs  
BY 16115833 - DM NEONATOLOGY ASHOKRAJA

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INTRODUCTION

In ancient times, birth attendants tried to remove the secretions by using a cloth or by blowing through the mouth and nose, or using a finger to remove secretions.(1) Then as the science of Resuscitation started developing, the initial resuscitation practices started from routine suctioning of mouth and nose using a suction machine or bulb syringe. Now the Recent NRP (Neonatal Resuscitation programme) 2011 guidelines states that clear the airway if necessary and it can be done with a suction catheter, bulb syringe or by wiping with a cloth.(2)

In Indian context all the three methods are prevalent in different settings throughout the country. WHO and NRHM raised concerns about sterilizing the bulb syringes and the chances of infection using a towel. A Disposable suction catheter or deLee's mucus trap connected to a suction machine is used in many

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Govt. Rajaji Hospital,  
Madurai-20. Dated: 12.2013

Institutional Review Board / Independent Ethics Committee.  
Dr. N. Mohan, M.S., F.I.C.S., F.A.I.S.,  
Dean, Madurai Medical College &  
Govt. Rajaji Hospital, Madurai 625020. **Convenor**

**Sub:** Establishment-Govt. Rajaji Hospital, Madurai-20-  
Ethics committee-Meeting Minutes- for November 2013  
Approved list-regarding.

The Ethics Committee meeting of the Govt. Rajaji Hospital, Madurai was held on 18.11.2013, Monday at 10.00 am to 12.00 noon at the Anaesthesia Seminar Hall, Govt. Rajaji Hospital, Madurai. The following members of the committee have attended the meeting.

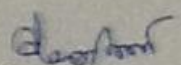
1. Dr. V. Nagarajan, M.D., D.M (Neuro) Ph: 0452-2629629 Cell.No 9843052029	Professor of Neurology (Retired) D.No.72, Vakkil New Street, Simmakkal, Madurai -1	Chairman
2. Dr. Mohan Prasad, M.S M.Ch Cell.No.9843050822 (Oncology)	Professor & H.O.D of Surgical Oncology(Retired) D.No.72, West Avani Moola Street, Madurai -1	Member Secretary
3. Dr. I. Jeyaraj, M.S., (Anatomy) Cell.No 9566211947	Director & Professor Institute of Anatomy /V.P Madurai Medical College	Member
4. Dr. Parameswari M.D (Pharmacology) Cell.No.9994026056	Director of Pharmacology Madurai Medical College	Member
5. Dr.S. Vadivel Murugan, MD., (Gen.Medicine) Cell.No 9566543048	Professor of Medicine Madurai Medical College	Member
6. Dr.S. Meenakshi Sundaram, MS (Gen.Surgery) Cell.No 9842138031	Professor & H.O.D of Surgery i/c Madurai Medical College	Member
7. Mrs. Mercy Immaculate Rubalatha, M.A., Med., Cell. No. 9367792650	50/5, Corporation Officer's quarters, Gandhi Museum Road, Thamukam, Madurai-20	Member
8. Thiru. Pala. Ramasamy, BA.,B.L., Cell.No 9842165127	Advocate, D.No.72.Palam Station Road, Sellur, Madurai -2	Member
9. Thiru. P.K.M. Chelliah, B.A Cell.No 9894349599	Businessman, 21 Jawahar Street, Gandhi Nagar, Madurai-20	Member


The following Project was approved by the committee

Name of P.G.	Course	Name of the Project	Remarks
Dr. I. Ashokraja	PG in D.M. (Neonatology) Madurai Medical College and Government Rajaji Hospital, Madurai-20	A Randomised control trial on Routine suction versus NO suction in vigorous term neonates at birth	Approved


Please note that the investigator should adhere the following: She/He should get a detailed informed consent from the patients/participants and maintain it Confidentially.

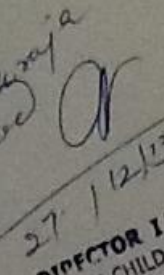
1. She/He should carry out the work without detrimental to regular activities as well as without extra expenditure to the institution or to Government.
2. She/He should inform the institution Ethical Committee, in case of any change of study procedure, site and investigation or guide.
3. She/He should not deviate the area of the work for which applied for Ethical clearance. She/He should inform the IEC immediately, in case of any adverse events or Serious adverse reactions.
4. She/He should abide to the rules and regulations of the institution.
5. She/He should complete the work within the specific period and if any Extension of time is required He/She should apply for permission again and do the work.
6. She/He should submit the summary of the work to the Ethical Committee on Completion of the work.
7. She/He should not claim any funds from the institution while doing the work or on completion.
8. She/He should understand that the members of IEC have the right to monitor the work with prior intimation.

  
Member Secretary      Chairman  
Ethical Committee

  
DEAN/Convenor  
Govt. Rajaji Hospital,  
Madurai- 20.

To  
The above Applicants  
-thru. Head of the Department concerned

  
20/12/13

  
27/12/13  
DIRECTOR I/C  
INSTITUTE OF CHILD HEALTH &  
RESEARCH CENTRE  
GOVT. RAJAJI HOSPITAL  
MADURAI - 625 020



[illegible]



79	1	1	31	2.5000	38	1.00	1		8.00	1		65	69.00	76.00	80.00	83.00	86.00	90.00	91.00	92.00	94.00	95.00	96.00	96.00	95.00	97.00	09:19:30	00:06:04	00:08:15	00:10:25	130	126.00	133.00	140.00	146.00	136.00	127.00	117.00	144.00	149.00	131.00	136.00	128.00	124.00	
80	2	1	22	2.7500	38	1.00	1		9.00	1				79.00	77.00	84.00	90.00	91.00	93.00	96.00	95.00	96.00	97.00	98.00	98.00	99.00	09:50:46	00:05:19	00:07:59	00:08:23			137.00	151.00	161.00	166.00	151.00	156.00	147.00	143.00	112.00	144.00	133.00	133.00	149.00
81	2	1	27	3.2500	38	1.00	1		9.00	1			80.00	84.00	85.00	92.00	95.00	97.00	95.00	95.00	97.00	98.00	98.00	99.00	100.00	100.00	10:34:50	00:03:03	00:05:35	00:06:18		152.00	177.00	170.00	173.00	168.00	169.00	157.00	161.00	157.00	150.00	141.00	169.00	179.00	169.00
82	2	1	20	2.0000	39	1.00	7		9.00	1			73.00	78.00	82.00	85.00	87.00	86.00	89.00	94.00	96.00	89.00	91.00	97.00	97.00	98.00	09:51:35	00:05:03	00:08:11	00:09:27			132.00	144.00	152.00	148.00	146.00	154.00	140.00	135.00	153.00	139.00	156.00	136.00	138.00
84	1	1	23	3.4000	38	1.00	1	6	8.00	1			76.00	80.00	83.00	89.00	92.00	95.00	96.00	96.00	98.00	97.00	96.00	97.00	96.00	09:05:04	00:04:10	00:06:04	00:06:54			120.00	141.00	143.00	147.00	137.00	151.00	151.00	153.00	140.00	149.00	144.00	146.00		
85	2	1	28	2.7000	38	1.00	4	3	9.00	1			76.00	80.00	85.00	88.00	90.00	93.00	96.00	96.00	97.00	96.00	97.00	98.00	96.00	97.00	09:28:26	00:04:18	00:06:36	00:07:28				149.00	161.00	158.00	158.00	162.00	179.00	181.00	168.00	161.00	170.00	168.00	157.00
86	1	2	25	3.7500	38	1.00	1		8.00	1				77.00	80.00	82.00	84.00	90.00	92.00	92.00	93.00	95.00	95.00	96.00	96.00	97.00	09:12:08	00:07:29	00:08:42	00:10:28				154.00	154.00	168.00	160.00	156.00	144.00	145.00	140.00	143.00	152.00	154.00	152.00
87	1	2	30	3.2500	38	1.00	1		8.00	3	3.00	66	70.00	75.00	78.00	80.00	83.00	85.00	87.00	89.00	92.00	94.00	95.00	96.00	97.00	97.00	09:53:40	00:06:26	00:10:28	00:11:54	110	138.00	138.00	141.00	155.00	145.00	136.00	154.00	151.00	146.00	148.00	146.00	162.00	154.00	152.00
88	2	1	30	3.5000	38	1.00	1	5	9.00	1			55.00	60.00	68.00	75.00	79.00	81.00	83.00	84.00	87.00	92.00	93.00	95.00	96.00	97.00	10:20:22	00:10:19	00:11:40	00:13:00				148.00	154.00	158.00		162.00	138.00	158.00	110.00	165.00	164.00	134.00	162.00
91	1	1	22	3.0000	38	1.00	1		8.00	1			77.00	83.00	86.00	92.00	94.00	96.00	95.00	97.00	98.00	100.00	98.00	97.00	98.00	98.00	10:06:27	00:04:03	00:04:38	00:06:36		128.00	136.00	150.00	165.00	171.00	163.00	167.00	173.00	178.00	173.00	164.00	164.00	165.00	163.00
92	2	2	25	2.1500	38	1.00	1		9.00	1			67.00	72.00	74.00	78.00	81.00	85.00	87.00	90.00	92.00	93.00	94.00	97.00	98.00	99.00	10:08:58	00:08:19	00:10:00	00:12:30		120.00	142.00	158.00	165.00	169.00	162.00	153.00	167.00	177.00	169.00	165.00	161.00	166.00	168.00
93	1	2	20	3.2000	38	2.00	1		8.00	1				85.00	94.00	95.00	95.00	96.00	97.00	98.00	97.00	98.00	97.00	98.00	100.00	99.00	10:44:15	00:03:00	00:04:17	00:05:39			138.00	161.00	165.00	177.00	176.00	183.00	179.00	179.00	174.00	167.00	166.00	166.00	168.00
95	1	1	24	3.0000	38	1.00	1	6	9.00	1			68.00	72.00	78.00	80.00	82.00	86.00	88.00	90.00	92.00	94.00	95.00	96.00	94.00	95.00	09:19:02	00:07:08	00:10:29	00:11:17		146.00	152.00	156.00	160.00	156.00	153.00	154.00	156.00	162.00	145.00	158.00	144.00	151.00	158.00
96	1	1	27	3.4000	38	1.00	4	3	9.00	1		76	81.00	85.00	92.00	93.00	94.00	95.00		96.00	97.00	98.00	96.00	97.00	97.00	98.00	09:25:22	00:03:03	00:03:55	00:06:39		132.00	145.00	165.00	160.00	193.00	185.00		180.00	175.00	178.00	179.00	199.00	199.00	191.00
97	2	1	27	3.5000	38	1.00	5		9.00	3	3.00		77.00	80.00	82.00	85.00	87.00	91.00	93.00	94.00	93.00	95.00	96.00	97.00	97.00	98.00	10:00:02	00:05:19	00:07:11	00:10:31		162.00	167.00	153.00	164.00	168.00	149.00	142.00	141.00	129.00	150.00	156.00	156.00	159.00	
98	2	1	25	3.3000	38	1.00	1		9.00	1			68.00	74.00	76.00	81.00	81.00	84.00	86.00	89.00	91.00	93.00	95.00	96.00	97.00	97.00	09:20:33	00:07:20	00:10:12	00:11:46			148.00	146.00	156.00	158.00	164.00	189.00	175.00	188.00	188.00	173.00	173.00	162.00	164.00
99	2	1.	25	3.0000	38	1.00	1		9.00	1			76.00	80.00	84.00	86.00	90.00	92.00	95.00	97.00	98.00	98.00	97.00	97.00	97.00	97.00	10:12:08	00:07:16	00:07:09	00:07:45					145.00	154.00	150.00	147.00	143.00	138.00	147.00	151.00	146.00	152.00	143.00
100	2	2.	23	3.0000	38	1.00	1		9.00	1			49.00	58.00	40.00	61.00	76.00	77.00	80.00	83.00	85.00	84.00	86.00	94.00	95.00	95.00	09:14:05	00:09:18	00:12:06	00:13:40			160.00	122.00	104.00	142.00	155.00	135.00	166.00	152.00	143.00	154.00	161.00	159.00	156.00
101	2	2.	21	4.0000	38	1.00	5		9.00	1			65.00	71.00	78.00	81.00	85.00	86.00	88.00	91.00	93.00	92.00	95.00	96.00	98.00	99.00	09:48:36	00:06:25	00:09:23	00:12:27			122.00	168.00	145.00	164.00	174.00		170.00	164.00	169.00	166.00	163.00	167.00	160.00
102	2	1.	24	3.0000	38	1.00	1	6	9.00	3	4.00			80.00	84.00	88.00	92.00	98.00	96.00	95.00	94.00	96.00	97.00	98.00	96.00	97.00	09:18:45	00:05:28	00:06:01	00:08:55			165.00	182.00	157.00	160.00	159.00	170.00	162.00	176.00	178.00	179.00	170.00	179.00	168.00
103	2	1.	18	3.0000	38	1.00	4	2	9.00	1			72.00	77.00	81.00	85.00	91.00	91.00	93.00	95.00	94.00	95.00	96.00	96.00	96.00	97.00	09:34:10	00:05:00	00:07:24	00:08:46		161.00	155.00	113.00	176.00	171.00	163.00	160.00	166.00	163.00	158.00	154.00	124.00	146.00	
104	2	1.	24	3.0000	38	1.00	1		9.00	1			70.00	78.00	82.00	86.00	85.00	88.00	90.00	92.00	94.00	95.00	96.00	98.00	97.00	96.00	10:01:14	00:06:21	00:08:58	00:11:06					168.00	161.00	159.00	166.00	159.00	154.00	157.00	157.00	155.00	154.00	
106	1	2.	31	2.0000	38	1.00	1		9.00	1			75.00		84.00	86.00	91.00	93.00	94.00	95.00	95.00	96.00	97.00	97.00	96.00	97.00	09:05:24	00:05:19	00:06:25	00:08:40		143.00		160.00	162.00	148.00	168.00	134.00	150.00	158.00	153.00	164.00	144.00	160.00	131.00
108	2	1.	24	3.0000	38	1.00	1		9.00	1		76	83.00	85.00	87.00	86.00	87.00	90.00	94.00	95.00	96.00	98.00	98.00	96.00	98.00	98.00	09:28:31	00:05:09	00:07:40	00:09:22	106	167.00	168.00	158.00	158.00	162.00	158.00	180.00	148.00	162.00	156.00	162.00	154.00	124.00	134.00
109	2	1.	23	3.0000	38	1.00	1		9.00	1			54.00	60.00	65.00	69.00	73.00	79.00	83.00	84.00	86.00	92.00	94.00	96.00	96.00	97.00	09:41:11	00:09:30	00:10:40	00:12:18			170.00	168.00	168.00	170.00	156.00	153.00	146.00	144.00	146.00	142.00	145.00	146.00	141.00
110	2	2.	23	2.0000	38	1.00	1		9.00	1			71.00	75.00	81.00	83.00	87.00	93.00	93.00	96.00	97.00	95.00	97.00	98.00	99.00	98.00	11:05:06	00:06:14	00:06:25	00:08:43		125.00	151.00	127.00	176.00	167.00	156.00	145.00	141.00	154.00	148.00	139.00	152.00	152.00	129.00
111	2	2.	25	2.0000	39	1.00	1		9.00	1				76.00	81.00	84.00	86.00	89.00	91.00	93.00	92.00	94.00	93.00	94.00	97.00	97.00	09:27:50	00:06:11	00:08:44	00:13:22			155.00	133.00	127.00	141.00	140.00	133.00	149.00	146.00	138.00	145.00	149.00	142.00	
112	2	1.	29	4.0000	38	1.00	1		9.00	1			64.00	66.00	73.00	77.00	83.00	86.00	84.00	86.00	93.00	94.00	95.00	93.00	93.00	96.00	09:56:20	00:06:20	00:09:30	00:14:10			166.00	134.00		158.00	154.00	163.00	168.00	151.00	162.00	161.00	149.00	161.00	153.00
113	2	2.	27	2.0000	38	1.00	1		9.00	1			73.00	79.00	81.00	84.00	86.00	90.00	92.00	96.00	98.00	97.00	98.00	99.00	97.00	100.00	10:41:55	00:05:29	00:07:																